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ENVIRONMENTAL ASSESSMENT BOARD

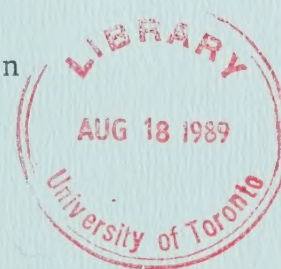
VOLUME: 120

DATE: Tuesday, August 8th, 1989

BEFORE: M.I. JEFFERY, Q.C., Chairman

E. MARTEL, Member

A. KOVEN, Member



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HEARING ON THE PROPOSAL BY THE MINISTRY OF NATURAL
RESOURCES FOR A CLASS ENVIRONMENTAL ASSESSMENT FOR
TIMBER MANAGEMENT ON CROWN LANDS IN ONTARIO

IN THE MATTER of the Environmental
Assessment Act, R.S.O. 1980, c.140;

- and -

IN THE MATTER of the Class Environmental
Assessment for Timber Management on Crown
Lands in Ontario;

- and -

IN THE MATTER OF a Notice by the
Honourable Jim Bradley, Minister of the
Environment, requiring the Environmental
Assessment Board to hold a hearing with
respect to a Class Environmental
Assessment (No. NR-AA-30) of an
undertaking by the Ministry of Natural
Resources for the activity of timber
management on Crown Lands in Ontario.

Hearing held at the Ramada Prince Arthur
Hotel, 17 North Cumberland St., Thunder
Bay, Ontario, on Tuesday, August 8th,
1989, commencing at 1:00 p.m.

VOLUME 120

BEFORE:

| | |
|------------------------------|----------|
| MR. MICHAEL I. JEFFERY, Q.C. | Chairman |
| MR. ELIE MARTEL | Member |
| MRS. ANNE KOVEN | Member |

A P P E A R A N C E S

| | |
|-----------------------|----------------------------|
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| MR. R. COSMAN) | ASSOCIATION and ONTARIO |
| MS. E. CRONK) | LUMBER MANUFACTURERS' |
| MR. P.R. CASSIDY) | ASSOCIATION |
| MR. H. TURKSTRA | ENVIRONMENTAL ASSESSMENT |
| | BOARD |
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| MR. B.R. ARMSTRONG | ANGLERS & HUNTERS |
| MR. G.L. FIRMAN | |
| MR. D. HUNTER | NISHNAWBE-ASKI NATION |
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| MS. M. SWENARCHUK) | FORESTS FOR TOMORROW |
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| MR. R. BARNES) | ASSOCIATION |
| MR. R. EDWARDS) | NORTHERN ONTARIO TOURIST |
| MR. B. McKERCHER) | OUTFITTERS ASSOCIATION |

APPEARANCES: (Cont'd)

| | |
|--|--|
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| MR. D. COLBORNE | GRAND COUNCIL TREATY #3 |
| MR. R. REILLY | ONTARIO METIS & ABORIGINAL ASSOCIATION |
| MR. H. GRAHAM | CANADIAN INSTITUTE OF FORESTRY (CENTRAL ONTARIO SECTION) |
| MR. G.J. KINLIN | DEPARTMENT OF JUSTICE |
| MR. S.J. STEPINAC | MINISTRY OF NORTHERN DEVELOPMENT & MINES |
| MR. M. COATES | ONTARIO FORESTRY ASSOCIATION |
| MR. P. ODORIZZI | BEARDMORE-LAKE NIPIGON WATCHDOG SOCIETY |
| MR. R.L. AXFORD | CANADIAN ASSOCIATION OF SINGLE INDUSTRY TOWNS |
| MR. M.O. EDWARDS | FORT FRANCES CHAMBER OF COMMERCE |
| MR. P.D. McCUTCHEON | GEORGE NIXON |

(iii)

APPEARANCES: (Cont'd)

MR. C. BRUNETTA

NORTHWESTERN ONTARIO
TOURISM ASSOCIATION

I N D E X O F P R O C E E D I N G S

Submissions:

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I N D E X O F E X H I B I T S

| <u>Exhibit No.</u> | <u>Description</u> | <u>Page No.</u> |
|--------------------|---|-----------------|
| 707 | Supplement to Curriculum Vitae of Peter Kingsbury. | 20089 |
| 708 | Curriculum Vitae of Leonard Ritter. | 20089 |
| 709 | Hard copy of series of slides numbered A through J. | 20090 |
| 710 | Prints of photographs numbered 1 through 5 to be referred to by Dr. Ritter in evidence-in-chief. | 20090 |
| 711 | Hard copy of series of overheads numbered A through D to be referred to by Mr. Kingsbury in evidence-in-chief. | 20091 |
| 712 | Article entitled: Pesticides in Forestry and Agriculture, Effects on Aquatic Habitats authored by Kingsbury, et al. | 20091 |

1 ---Upon commencing at 1:10 p.m.

2 THE CHAIRMAN: Good afternoon. Welcome
3 back. Please be seated.

4 Ladies and gentlemen, I think we will
5 start off the proceedings this afternoon with some of
6 the outstanding procedural matters that we left before
7 the summer break.

8 First and foremost will be the discussion
9 of the manner in which and the terms under which the
10 Board will call Dean Baskerville and, in this regard,
11 as you are aware, the Board has retained legal counsel,
12 Mr. Herman Turkstra, to represent the Board in
13 connection with the calling of this witness and also
14 presumably to represent this witness when that witness
15 is called.

16 Now, I understand that there have been
17 meetings with Mr. Turkstra subsequent to the last
18 sitting and at those meetings there have been, I
19 presume, certain matters clarified.

20 The way the Board intends to proceed
21 today is to call upon Mr. Turkstra to raise this matter
22 formally before us and to indicate what matters the
23 Board should be dealing with at this time.

24 Mr. Turkstra?

25 MR. TURKSTRA: Well, Mr. Chairman, notice

1 was given to the participants and groups who were
2 parties and an informal meeting was held at the Board's
3 offices. At that time the process that developed, I
4 think can be said by consensus, was that my associate
5 Marcia Valiante and I would review the transcripts and
6 the exhibits and attempt from that review to develop a
7 list of subjects and a list of exhibits which we felt
8 directly came within the scope of the Board's order,
9 and that once we had assembled that list we would send
10 the list, the transcript references with the assistance
11 of Mr. Mander, to all of the parties and request that
12 they comment on it.

13 As of today I really only have one
14 comment on the exhibits and that is from counsel for
15 Forests for Tomorrow. But I think sufficient time has
16 gone by for me to be able to say that the list of
17 exhibits and subject matters that I proposed have not
18 produced any significant concerns expressed on the
19 parts of other counsel.

20 I expect, having said that, if there were
21 an agreement it will be prompted this week and/or in
22 the near future and under normal circumstances my next
23 step would be to meet with Dean Baskerville. And we
24 had originally expected that we might be able to do
25 that toward the end of the summer and to turn over to

1 him the transcript references that we have accumulated.
2 They have been bound to give you some idea of the
3 scope. Mr. Chairman, that's -- does the Board have a
4 copy of it?

5 The transcripts have been bound and
6 unless I am instructed otherwise by the Board, my
7 scheduling would be that when the Ministry case is
8 finished it would be my understanding that Dr.
9 Baskerville will be called immediately at the
10 conclusion of the MNR case.

11 I would like the Board perhaps to give
12 some guidance as to where it might wish to hear the
13 evidence of Dr. Baskerville. What I noted in the last
14 meeting is that virtually all counsel come from the
15 Toronto area and I was going to propose that you might
16 at least give some consideration to having his evidence
17 heard in Toronto from the point of view of convenience
18 of the parties. And not knowing how long his evidence
19 will take, it's certainly one stop for him to come
20 there.

21 THE CHAIRMAN: That's one of the
22 considerations, Mr. Turkstra.

23 Has any thought by yourself or other
24 counsel been given to how long Dean Baskerville's
25 examination might in fact take?

1 MR. TURKSTRA: No, sir. As I say, the
2 only thing that we have been able to do is end up with
3 about six pages of topics, and if I were to take a
4 rough guess I would say somewhere in direct between a
5 week or two.

6 THE CHAIRMAN: That's for direct
7 evidence?

8 MR. TURKSTRA: Yes. I wouldn't speculate
9 on cross-examination.

10 THE CHAIRMAN: Has any indication been
11 given, Mr. Turkstra, by Dean Baskerville as to how long
12 he might be available?

13 MR. TURKSTRA: No, but he indicated that
14 he understood that it may be a several-week operation
15 and we have to work that I think perhaps around his
16 academic responsibilities.

17 I think until I get a better handle on
18 how the Ministry's case might be proceeding and
19 approximately when he might be called, it is difficult
20 for me to...

21 THE CHAIRMAN: Well, given the fact that
22 the Ministry's case might be finished - if we can be so
23 bold as to even speculate that it might ever be
24 finished - in October of this year, would that in any
25 way, and I assume that the university is in session

1 then, has any consideration been given, if that did in
2 fact occur, would he be available?

3 MR. TURKSTRA: That was the date that I
4 was originally working on and that seemed to be
5 workable for him. We haven't got down to the specific
6 weeks and times, but with that indication I will go
7 back to him and let you know if there is a problem.

8 There are two outstanding matters that I
9 would like to deal with, if I could today, in
10 connection with this.

11 The first is that the letter from counsel
12 for Forests for Tomorrow raises the fact that in the
13 list of exhibits that I propose to have Dr. Baskerville
14 review have gone beyond the audit itself and the study
15 on that and had, in fact, proposed seven exhibits: 4,
16 16, 58, 135, 378, 405 and 425 and what Michelle
17 Swenarchuk properly commented on is that several of
18 those are not an integral part of the audit, but it was
19 our view that those exhibits were introduced as a part
20 of the discussion on the audit and contain material
21 directly relating to it, and unless the Board rules
22 otherwise I will be inclined to ask Dr. Baskerville to
23 be ready to answer questions about that.

24 The second issue is the scope of the
25 cross-examination and the Board's order in its notice

1 to parties of March 9th in the second paragraph said
2 that:

3 "Dean Baskerville's evidence will be
4 confined to a discussion of his audit
5 report and the discussion of that
6 part of the Ministry of Natural Resources
7 October action plan which pertains to his
8 audit report and nothing further."

9 I take that to be a direction to myself
10 as to the evidence to be given in-chief and I have some
11 concern about the Board limiting the scope of
12 cross-examination to matters that are directly set out
13 within that term.

14 I have no problem with conducting my own
15 examination of that, but I do have some difficulty in
16 saying that. If the word "evidence" in that clause
17 means evidence-in-chief then I have no problem with
18 that, but if it means cross-examination or total
19 evidence, then there may very well be difficulty in
20 terms of the way in which the judges are describing the
21 right of cross-examination.

22 And in that connection, perhaps before we
23 all go home today, I thought it might be helpful if
24 there is a clear understanding of what the rights of
25 cross-examination are going to be of the parties and

1 also a very clear indication as to where the parties
2 stand on whether or not any of the parties will be
3 calling Dr. Baskerville.

4 In that connection, it is my submission
5 to you that the only reason for the Board to call Dr.
6 Baskerville is that it appeared that no party was going
7 to call him and that his evidence would be of
8 assistance to the Board taking into account the nature
9 of the Board's function. And it is my submission to
10 you that if any of the parties intend to call Dr.
11 Baskerville it would not be appropriate for me to
12 proceed with what I am doing, but I should stop that.

13 And I think it flows from that that if
14 the Board's March order is to remain, then it virtually
15 requires a commitment from other parties not to call
16 him. And if they intend to call him, then I would like
17 to make some submissions as to whether or not that
18 order might very well be rescinded because I see some
19 difficulties with that.

20 In terms of the scope of
21 cross-examination, it would be my submission to you
22 that when a cross-examining party goes beyond the
23 direct evidence which the Board is calling Dr.
24 Baskerville for, they are in substance dealing with a
25 person who becomes notionally, in my submission, their

1 witness and at that point their examination of him on
2 other subject matters should be by way of
3 examination-in-chief; that is to say, not the kind of
4 cross-examination that you might get if he was another
5 party.

6 And it also goes without saying that
7 since, as Mr. Freidin says, there is no property in a
8 witness, the fact that I am preparing Dr. Baskerville
9 for his appearances here as a witness for the Board in
10 no way prevents any person from talking to Dr.
11 Baskerville or asking him about his evidence or his
12 views. The fact is he is not under my control as Board
13 counsel and I can't restrain him from talking to other
14 people. So that if the cross-examination -- the bottom
15 line in my submissions are this: If the
16 cross-examination is intended to go beyond the scope of
17 the evidence that seems to be generally agreed as being
18 within the scope of the Board's order, then when the
19 cross-examiner ventures into that field they enter into
20 areas where they should be treated as if they were
21 examining their own witness in-chief at that stage.

22 And that would be subject to the Board's
23 rulings on relevance and weight of the evidence, but I
24 think those rules ought to be clearly understood before
25 we get too far down the path.

1 I think, Mr. Chairman, those are the
2 submissions that I wanted to make to get the
3 submissions going.

4 THE CHAIRMAN: All right. Let's proceed
5 in this way: The Board, as I think all the parties are
6 aware, decided that it would call Dean Baskerville
7 because it appeared to the Board after several months
8 of inquiry amongst the various parties if anyone else
9 wished to call him that he would not in fact be called
10 by any other party.

11 The Board felt that it would benefit the
12 hearing and the Board's deliberations to have
13 clarification from Dean Baskerville himself as to what
14 he meant in terms of the language used in the audit
15 document, and it was for that reason that the Board
16 indicated that it would consider calling this witness
17 as the Board's witness.

18 Now, if it turns out that another party
19 is intending to call Dean Baskerville - and the Board
20 appreciates that it has no property rights in a
21 witness - if another party wishes to call Dean
22 Baskerville they are at liberty to do so provided, of
23 course, that his evidence is relevant to the subject
24 matter of this hearing.

25 If another party wishes to call Dean

1 Baskerville, the Board wants to know that and wants the
2 undertaking from that party to in fact call this
3 witness because, if that is the case, then the Board
4 may well decide that it will not call Dean Baskerville
5 as its witness.

6 The purpose in having Dean Baskerville
7 before the Board is to clarify certain aspects which
8 have arisen in evidence already and have, in the
9 Board's view, been the subject of some speculation as
10 to what he did or did not mean in terms of his audit
11 report.

12 Now, I understand from correspondence
13 that has been submitted to you, Mr. Turkstra, that one
14 of the parties, the Federation of Anglers & Hunters,
15 had indicated that they might in fact wish to call Dean
16 Baskerville. And again, if that is the case, then
17 perhaps Mr. Hanna and Dr. Quinney, you can indicate to
18 us at this time that that is your intention or is not
19 your intention because that will definitely affect the
20 way the Board wishes to proceed in this matter.

21 MR. HANNA: Mr. Chairman, I would like to
22 give you a yes or no answer; unfortunately, it is not a
23 yes or no circumstance. I believe we are all groping
24 with much the same problem, we are trying to determine
25 the scope and nature of the evidence that Dr.

1 Baskerville will put forward.

2 The Board's ruling is quite clear in
3 terms of what the evidence is that it's looking for
4 from Dr. Baskerville, however -- and I believe Ms.
5 Murphy actually drew this to the Board's attention when
6 she was speaking with respect to the action plan in
7 that the action plan only goes to the essence of many
8 parts of the application and, therefore, the scope of
9 the evidence that he is going to bring forward is still
10 somewhat uncertain in terms of how far he actually will
11 go in the evidence that he gives through the Board as
12 directed by Mr. Turkstra.

13 As Mr. Turkstra has indicated, he has
14 done an initial survey of the transcripts and there is
15 a voluminous amount of information brought forward
16 whereby Dr. Baskerville's name has been used or
17 implicated and I would suggest to you that the
18 Federation is still in the process of looking through
19 the transcripts for possibly other places whereby he
20 may be implicated further in terms of the evidence that
21 he might want to -- the Board might want to have
22 clarification on.

23 The Ontario Federation of Anglers &
24 Hunters' position is that Dr. Baskerville, if not the
25 expert, is one of the experts in the country in terms

1 of forest management. He has -- the people of Ontario
2 have already invested a substantial amount of money in
3 his knowledge of the system, even if it was the system
4 prior to the 1986 forest planning manual.

5 There is, in our view, nobody in Canada
6 that has the same amount of knowledge and experience,
7 and given that investment and the investment the Board
8 will be making in bringing him forward, we would be
9 quite concerned if the scope of his evidence was
10 confined such that the people of Ontario are not
11 given the full benefit of the knowledge that he offers.

12 And I guess the position of the
13 Federation is when the circumstance arises in
14 cross-examination that the scope of cross-examination
15 was limited in such a way that the full benefit of his
16 knowledge was not provided, that the Federation would
17 at that time contemplate retaining Dr. Baskerville.

18 Now, I believe Mr. Turkstra has raised,
19 in my view, a very interesting issue and that is this
20 question of what Dr. Baskerville's status would be once
21 cross-examination had exceeded the scope of the direct
22 evidence that he would be preparing him for.

23 I would say to you at this time that if
24 the Board was of the view, as I believe has been
25 indicated by Mr. Turkstra, that if during

1 cross-examination once he is asked questions outside of
2 what material Mr. Turkstra had prepared him for, that
3 that would be treated basically as evidence-in-chief
4 and likewise that there would be the opportunity to
5 give Dr. Baskerville some pre-notice of those questions
6 coming so that he can prepare himself, then I see no
7 reason why the Ontario Federation of Anglers & Hunters
8 would contemplate calling Dr. Baskerville.

9 In fact, as I believe I submitted to the
10 Board earlier in this matter, in my view I think there
11 is a certain benefit in having him in that somewhat
12 impartial role. I believe in fact Ms. Murphy also made
13 reference to fairness in having Dean Baskerville called
14 by the Board.

15 So I guess basically my position is at
16 the present time, if the Board does concur with the
17 view that Mr. Turkstra has brought forward, I cannot
18 see the need for the Federation to call Dr.
19 Baskerville.

20 By the same token, if the Federation does
21 become restricted in any way in its cross-examination
22 of Dr. Baskerville, we will at that time endeavour
23 possibly to call him as a witness.

24 THE CHAIRMAN: Any other parties have any
25 comments on these issues?

1 MR. CASSIDY: Go ahead, Mr. Castrilli.

2 MR. CASTRILLI: Mr. Chairman, there was a
3 matter raised by Mr. Turkstra that I want to briefly
4 direct your attention to.

5 He referred to a letter that was sent to
6 him in July with respect to the fact that four other
7 exhibits authored by Dr. Baskerville are in fact in
8 evidence, and we would also note that a number of those
9 exhibits deal with matters that are in fact also dealt
10 with in the audit.

11 Having said that, we are somewhat
12 concerned about Mr. Turkstra's suggestion that any
13 examination beyond what is essentially Exhibit 16 or
14 what is to be found in the Board order of March 9th
15 becomes not cross-examination but examination-in-chief.
16 I would submit in the circumstances it would be highly
17 unlikely if not unreasonable to ask the same party to
18 both cross-examine and examine the same witness with
19 respect to the same matters.

20 I would simply ask that the Board's order
21 be expanded to include Exhibits 135, 378, 405 and 425
22 as a matter to be dealt with by Mr. Turkstra in-chief.

23 Those are my submissions.

24 MR. CASSIDY: Mr. Chairman, perhaps I can
25 take an opportunity now to address the Board in this

1 matter. In this matter we were operating on the
2 similar assumption to yourself, Mr. Chairman, and that
3 is that the Board was going to call Dean Baskerville
4 and that was going to be done at the end of MNR's case.
5 For reasons which I will indicate, we support
6 proceeding in that fashion.

7 However, we became aware of the
8 possibility that the Anglers & Hunters were
9 contemplating, and it appears now in some fashion they
10 are still contemplating calling him as their own
11 witness. The matter should be addressed by the Board
12 and it was brought to everyone's attention again by Ms.
13 Cronk.

14 It appears to us, however, our position
15 should - and for reasons of fairness which I will refer
16 to - should remain the same and that is that Dean
17 Baskerville should be called by the Board at the
18 conclusion of MNR's case, and perhaps I can state that
19 another way, prior to the commencement of any other
20 party's case.

21 It appears to us for reasons which have
22 readily appeared upon a review of the materials that
23 Mr. Turkstra and his associate have prepared that Dean
24 Baskerville has had a major impact on this issue, he
25 has had a lot of things to say, and it was actually

1 interesting to see the extent to which he has been
2 referred to in this evidence to date and, therefore, he
3 is in a unique position for all the reasons which I am
4 sure you are aware, and to comment on some of the
5 comments that have been made in this hearing on his
6 views as expressed in the audit report and others.

7 However, the reason why we feel he should
8 be called to give those comments by the Board and at
9 the end of MNR's case is simply for two major reasons,
10 because it is the fairest procedure.

11 The first is of course it would afford
12 all of the parties, not just our client, but everyone
13 within this room the opportunity to cross-examine him
14 on those views since his views were so widespread and
15 touched upon many of the issues that appear to have
16 surfaced in this hearing. It would afford the parties,
17 even within the confines of the material that Mr.
18 Turkstra has put together, the opportunity to have a
19 fairly wide range of discussion with him on those
20 matters. So, therefore, you would have every party in
21 the position of being equal; that is, they have equal
22 rights to cross-examination of him and obviously MNR
23 would have the opportunity to have their due reply.

24 And, secondly, it would also be fair to
25 all parties because every party would then be in a

1 position and would all be able to do that, of calling
2 evidence in their own cases to deal with Dean
3 Baskerville's evidence, if you will. If there is
4 something that they disagreed with with Dean
5 Baskerville or something that they agreed with and
6 wanted to support, every party would have that
7 opportunity.

8 If this were to be done at any other time
9 were it called during, for example, the Anglers &
10 Hunters' evidence, the parties proceeding the Anglers &
11 Hunters would not have that opportunity and it would
12 turn into a messy battle of having limited rights --
13 full rights of reply.

14 So, therefore, I think the Board's
15 original reasoning in that respect was fair, although I
16 note, as you have, that the whole reason why the Board
17 considered this route was to have Dean Baskerville's
18 views here because you were not getting an indication
19 from the other parties that they were going to call
20 Dean Baskerville.

21 I think I am getting a sense from hearing
22 Mr. Hanna this morning and reading the correspondence
23 that flowed that he is somehow concerned that the
24 Anglers & Hunters will not have the opportunity to
25 canvass all of the issues with Dean Baskerville and

1 that matter, I submit, goes directly to what Mr.
2 Turkstra was saying about the rights of cross-examining
3 Dean Baskerville.

4 As my colleague Mr. Tuer pointed out, one
5 of the overriding concerns that the Board should have
6 is to avoid the appearance. I stress the word
7 appearance because I am not suggesting for a minute
8 that the Board would do that; avoiding the appearance
9 of Dean Baskerville would be somehow judging this
10 matter, taking some sort of position that would be
11 regarded in reference to other witnesses or other
12 expert witnesses.

13 I would urge you to -- remind you of that
14 concern, but at the same time if there was full
15 cross-examination allowed of him beyond the matters
16 that were in his initial evidence as prepared by Mr.
17 Turkstra, then the Anglers & Hunters, I submit, would
18 be able to get into matters of import to them that may
19 not be in the evidence of Dean Baskerville.

20 Of course subject, and I stress this,
21 obviously to the rules of relevancy to this hearing and
22 to demonstrating that it be a matter fit for
23 cross-examination of Dean Baskerville that the Board
24 should entertain.

25 In that respect I respectfully disagree

1 with Mr. Turkstra's submission that there should be
2 some form of treating him and that part of his evidence
3 that goes beyond what Mr. Turkstra terms as
4 examination-in-chief.

5 I think the Board should be very leery of
6 restricting the rights of cross-examination of parties
7 other than of course to the questions of relevancy and
8 scope of the hearing. But in those contexts, I think
9 Mr. Hanna's concerns would, in large part, be met and
10 therefore he would not, I submit, find the need to call
11 Dean Baskerville as a witness.

12 I would support every attempt to be made
13 to have the Anglers & Hunters indicate right now
14 whether or not they wish to call Dean Baskerville as
15 their witness. I agree there is no property in a
16 witness, but I think at the end of the day after
17 hearing the evidence and all submissions there may be
18 an opportunity for them to so indicate; also, after
19 they have had the opportunity to review the material
20 prepared by Mr. Turkstra.

21 At least in my opinion, Mr. Chairman, it
22 would seem rather all encompassing. Obviously they
23 have their own agendas and may wish to introduce
24 further issues, but Mr. Turkstra I think did a fine job
25 of getting all the issues that were raised and are so

1 wide that perhaps it would alleviate the difficulty in
2 Anglers & Hunters calling extra evidence from Dean
3 Baskerville.

4 Then in my summation, Mr. Chairman, it is
5 my view that the Board should proceed as it had
6 originally intended and Anglers & Hunters should be
7 pressed to indicate with a greater degree of certainty
8 whether they wish to call Dean Baskerville, and perhaps
9 my comments and most of the other counsels' will assist
10 you in making that decision sooner rather than later.

11 Thank you.

12 THE CHAIRMAN: Mr. Freidin?

13 MR. FREIDIN: Mr. Chairman, in relation
14 to comments made by Mr. Cassidy I can concur with him
15 as to his submissions as to the timing of the evidence.
16 I would like to make a few remarks about limiting of
17 cross-examination of Dean Baskerville.

18 I share the concern voiced by Mr. Cassidy
19 about limiting the scope of the cross-examination. I
20 believe that it was my understanding as a result of the
21 meeting we had with Mr. Turkstra that parties were
22 going to be given the opportunity to indicate what
23 issues or matters they wished to raise or believed --
24 they wished to raise with Dean Baskerville and that
25 would go to Dean Baskerville along with transcripts, if

1 there were any in relation to that topic, or just an
2 indication that parties wanted him to know that they
3 would like to ask him questions in that area.

4 THE CHAIRMAN: Well, is it agreed or is
5 there a consensus amongst the parties that if the Board
6 were to proceed calling Dean Baskerville as its witness
7 that we would have a witness statement prepared for
8 Dean Baskerville and a clear indication from the other
9 parties as to which issues they wish to address; in
10 other words, sort of a witness statement/scoping
11 process to deal with him for two reasons, as I can see
12 it.

13 No. 1 to get a pretty good indication of
14 what may or may not be relevant to that examination;
15 and, secondly, to make sure that Dean Baskerville were
16 apprised in advance of what might be asked of him so
17 that (a) he can prepare, if he had to prepare, or could
18 decide that that was an area that he could not comment
19 on.

20 See, one of the problems with calling a
21 witness, and I would suggest that this witness is
22 different from other witnesses only in the respect that
23 his expertise covers many of the facets which are
24 before the Board as opposed to a circumscribed area of
25 expertise and, as a result, we want to avoid if we can

1 having a situation where Dean Baskerville who has not
2 been here for the preceding year's evidence is not put
3 in a position of having to read all of the transcripts
4 for the preceding year word for word as well as
5 examining each and every one of the exhibits in order
6 that parties can put questions to him which covers any
7 facet of what we have dealt with to this point in time.

8 That is a tall order for anybody,
9 particularly somebody who has been absent from the
10 hearing on a regular basis. And it would be the
11 Board's view, I think, that whatever Dean Baskerville
12 is going to deal with would be set out in a witness
13 statement and all of the parties would be required to
14 submit a list of issues they wish to canvass with him.

15 First of all, has something along those
16 lines, Mr. Turkstra, been discussed with the parties?

17 MR. TURKSTRA: That is almost exactly
18 what we agreed to at the meeting - I don't know if the
19 reporter can pick this up all right - but mm-hmm, I
20 think it's fair to say --

21 MR. FREIDIN: I think we agreed on both
22 the witness statement and scoping session but no
23 interrogatories--

24 MR. TURKSTRA: Right.

25 MR. FREIDIN: --was the discussion.

1 MR. TURKSTRA: Or consensus.

2 MR. CASSIDY: I think in fact the purpose
3 of the review of the transcript that Mr. Turkstra put
4 together was that parties would have the opportunity,
5 if they felt there were additional matters, to bring
6 them to Mr. Turkstra's attention now or as soon as
7 possible which we are all struggling with.

8 MR. FREIDIN: And I think the consensus
9 of the meeting was that except for exceptional
10 situations the issues that would be discussed or that
11 somebody would really want to, or would be fair to put
12 to Dean Baskerville for him to deal with were the
13 subject matters that arose in his report, the action
14 plan or any of the exhibits which were offered by him.

15 An example being, let's assume the
16 habitat supply analysis were not referred to in the
17 audit and in actual fact is, of course, the subject
18 matter in some of the other documents which were filed,
19 that would be a legitimate subject matter to indicate
20 we would like to ask questions on.

21 If it was something completely new, how
22 large is the moon, which isn't in any of the reports,
23 then there would be some question as to whether it was
24 really appropriate to have Dean Baskerville get up and
25 answer. So my remarks would be taken in light of those

1 comments.

2 But just going back to the -- I have some
3 concern about the statement by Mr. Turkstra that the
4 cross-examination would somehow turn into or be looked
5 upon as a direct examination if the cross-examination
6 went beyond what the evidence-in-chief was.

7 That would be fine I suppose if all the
8 evidence-in-chief covered every issue which everybody
9 wanted to deal with, but it might very well be that Mr.
10 Turkstra will not feel it is appropriate to do that and
11 for that reason I believe that a proper examination or
12 a full examination-in-chief controlled by the Board in
13 relation to the issue of relevancy as suggested by Mr.
14 Cassidy would be appropriate.

15 If the cross-examination in fact is
16 proceeded with in that fashion I believe that OFAH
17 would not be prejudiced in any way and that on some
18 reflection they could indicate to the Board that if
19 cross-examination was dealt with in that fashion that
20 they in fact would not wish to call Dean Baskerville
21 and we wouldn't have to deal with that as a potential
22 problem.

23 And, therefore, I would support Mr.
24 Cassidy in my submission that the OFAH should be
25 pressed to indicate one way or the other whether they

1 are going to call him.

2 I again am not here to act as counsel for
3 the OFAH but I think they should understand the
4 difference between undertaking to ask him to come and
5 undertaking that he will be here. I think the Board is
6 probably more concerned with the latter because if all
7 we get is, you know, they may ask him to show up, that
8 doesn't help the Board on which way to go on this
9 issue.

10 THE CHAIRMAN: No. The Board is
11 determined I think that Dean Baskerville appear. The
12 only thing that could really upset that resolve is the
13 fact that Dean Baskerville himself chooses not to
14 appear. He's outside the jurisdiction and I think he's
15 probably beyond the jurisdiction of this Board in that
16 sense.

17 As I understand it, Mr. Turkstra, he has
18 effectively indicated his willingness to appear should
19 the Board call him and may appear if some other party
20 called him. Is that your understanding?

21 MR. TURKSTRA: I don't know anything
22 about the latter part but the first part, he's prepared
23 to come as a witness for the Board.

24 THE CHAIRMAN: Okay. So given that, I
25 think we can all assume Dean Baskerville will at some

1 point make an appearance.

2 The question is: If we are going to call
3 him, then we expect no other party to do so; if we are
4 not going to call him, then we expect some other party
5 to undertake to do so and Mr. Turkstra can find out
6 whether or not Dean Baskerville would be willing to
7 come if some other party called him.

8 And we don't expect any duplication of
9 any of his evidence. We do not want to call Dean
10 Baskerville, go through the process of developing
11 witness statements and statements of issue, go through
12 the scoping process and then find out at the end of
13 that that another party still intends to call him.
14 That sort of circumvents the whole purpose upon which
15 the Board entered this discussion in the first place.

16 Now, going back to your comments, Mr.
17 Freidin. If the Board were to say that the direct
18 examination would be confined to the audit and the
19 collateral documents to the audit, including the
20 response by the Ministry, and that the
21 cross-examination would be open sufficiently to deal
22 with any of those documents raised in direct or any
23 issues which arise out of those documents in the
24 context of the witness statement as developed, would
25 that satisfy the various parties as to having the

1 opportunity to cross-examine on issues of importance to
2 them?

3 MR. FREIDIN: What was the last part of
4 your last comment? I got you as far as saying
5 cross-examination would be sufficient if it raised --
6 dealt with issues raised in direct or arise out of the
7 witness statement.

8 THE CHAIRMAN: Arise from the documents
9 raised in direct or in accordance with the issues
10 developed in terms of the witness statement.

11 In other words, we assume that a witness
12 statement is going to be developed which is going to be
13 based in part on the audit, the response to the audit
14 and all of the collateral documents.

15 MR. FREIDIN: I don't think that -- if in
16 fact -- when you say the documents raised in direct and
17 the issues developed in the witness statement, that
18 means only those matters which are written about in the
19 witness statement or are raised in oral evidence in
20 direct.

21 I do not think that would deal with the
22 problem because I have -- no one knows, for instance,
23 whether or not the evidence-in-chief or the witness
24 statement will or will not refer to, I'll give you the
25 same example, the habitat supply analysis. That

1 specific issue I do not believe was raised in either
2 the audit or in the action plan, it may not appear in
3 the witness statement, it may not come out of the mouth
4 of Dean Baskerville for very good reasons in
5 evidence-in-chief.

6 THE CHAIRMAN: Would it appear in a
7 statement of issues submitted by the parties that were
8 interested in that particular issue?

9 MR. FREIDIN: It should.

10 THE CHAIRMAN: Okay. So if it were
11 expanded to include statements of issue submitted by
12 the other parties, all of those things, and therefore
13 the Board would permit cross-examination on all of
14 that.

15 MR. FREIDIN: Sure, that is just
16 basically doing what in fact the Board has been doing
17 all along, saying raise it in your statement of issues.

18 THE CHAIRMAN: Subject only to relevancy.

19 MR. FREIDIN: Yes.

20 THE CHAIRMAN: The issue has to be
21 relevant to matters before the Board for determination.

22 MR. FREIDIN: Right. I think that would
23 cover it.

24 THE CHAIRMAN: Mr. Hanna?

25 MR. HANNA: Mr. Chairman, if it would be

1 appropriate if I could have maybe five or ten minutes
2 just to speak with Dr. Quinney on these matters and
3 come back and address the Board on this. I feel we are
4 closing --

5 THE CHAIRMAN: Okay, because we want to
6 try and settle this now because there is some work to
7 be done between now and October, if that is when Dean
8 Baskerville is going to be called, and that means Mr.
9 Turkstra will have to be presenting the transcripts and
10 other documentation to him and start working on witness
11 statements and we will also have to have the other
12 parties also working on statements of issue.

13 Just one minute, Mr. Turkstra. We want
14 to go around and make sure all of the parties have had
15 their say and then perhaps we will end with you.

16 Mr. Edwards?

17 MR. EDWARDS: Thank you, Mr. Chairman, I
18 will be very brief. If I might just make some comments
19 before Mr. Quinney and Mr. Hanna retire because I have
20 got to retire myself very shortly.

21 I would be quite content with the
22 proposal, however one issue raised by Mr. Turkstra
23 causes me a lot of concern and that is conversion of
24 the cross-examination into a direct examination and I
25 would --

1 THE CHAIRMAN: Well, we are not certainly
2 making a ruling on that at this point in time. That
3 was something put forward by Mr. Turkstra to see if
4 some limits could be put on the scope of this
5 examination, but that was more or less put forward for
6 discussion purposes at this stage.

7 MR. EDWARDS: Well, my discussion on that
8 is this, Mr. Chairman, that I think it would lead to an
9 unnecessary series of rulings and confrontations as to
10 whether one had strayed into a field where one should
11 be examining directly or cross-examining.

12 I think the Board's ordinary rulings with
13 respect to relevancy, repetition, et cetera would be
14 quite appropriate in the circumstances and if the
15 cross-examination is permitted openly and fully on the
16 issues raised, arising in the documents tendered, the
17 evidence-in-chief and the statements of issue, I think
18 that should squarely deal with the issues of relevancy.

19 As well it would be my submission it
20 would be appropriate to deal with it really in the
21 ordinary fashion rather than directing it --

22 THE CHAIRMAN: See that would be
23 presumably where the Board might get involved in terms
24 of ruling on the relevancy of the issue.

25 When statements of issue are put forward

1 and the Board takes a look at the statement of issues
2 and panels make their argument as to whether it's
3 relevant or not, the Board may on a particular issue
4 rule that that will be an issue that won't be addressed
5 by Dean Baskerville if in fact it felt it was
6 irrelevant to the matters for consideration before the
7 Board and we could sort of deal with it before he's
8 even called to speak.

9 Because I think in fairness to Dean
10 Baskerville, if the issues are deemed relevant he has
11 to prepare for them and Mr. Turkstra could be
12 counselling him on and providing the documentation from
13 the hearing relevant to that particular issue.

14 MR. EDWARDS: Mr. Chairman, if I may just
15 raise one separate issue while I'm here.

16 I would appreciate getting some direction
17 from the Board and other counsel as to when the
18 cross-examination on Panel 14 might be expected to
19 recommence. The last I heard it was anticipated that
20 the two witnesses, the pesticide witnesses may be as
21 long as two weeks. I'm just wondering if that has
22 changed at all?

23 MS. MURPHY: I'm going to be asking the
24 same question, Mr. Chairman, in my submissions because
25 we do have some concerns of Dr. Ritter's availability

1 of time.

2 THE CHAIRMAN: How long do you expect to
3 be in direct?

4 MS. MURPHY: I expect that we will be
5 half a day to one day in direct; closer to one day.

6 THE CHAIRMAN: For both the witnesses?

7 MS. MURPHY: That's right.

8 THE CHAIRMAN: Well, can we have an
9 indication from the other counsel as to how long they
10 might be in cross?

11 MS. CRONK: I wouldn't expect to be more
12 than half a day, sir.

13 THE CHAIRMAN: Mr. Castrilli?

14 MR. CASTRILLI: At this point, Mr.
15 Chairman, I would think at least two days.

16 THE CHAIRMAN: Two days. Ms. Seaborn?

17 MS. SEABORN: Two hours.

18 THE CHAIRMAN: Mr. Hanna?

19 MR. HANNA: About a day, Mr. Chairman.

20 THE CHAIRMAN: One day.

21 MR. HANNA: No more than a day.

22 THE CHAIRMAN: That is about four days.

23 MR. FREIDIN: I believe counsel for
24 Nishnawbe-Aski Nation and Treaty No. 3, who we did get
25 an estimate from the last time -- I think NAN was half

1 a day and Treaty No. 3 said a couple of hours.

2 THE CHAIRMAN: So that might be five
3 days. And yourself, Mr. Edwards?

4 MR. EDWARDS: I'm not proposing to
5 cross-examine.

6 THE CHAIRMAN: Okay. Looks like about
7 five days. So all together...

8 MS. MURPHY: You just made Dr. Ritter a
9 happy man.

10 THE CHAIRMAN: Sorry?

11 MS. MURPHY: You just made Dr. Ritter a
12 happy man.

13 THE CHAIRMAN: Well, with direct we may
14 be six days of evidence, but we should be able to
15 finish in six.

16 MR. EDWARDS: Thank you very much, Mr.
17 Chairman.

18 THE CHAIRMAN: Okay.

19 Ms. Seaborn?

20 MS. SEABORN: Mr. Chairman, I just have a
21 couple of comments on this issue.

22 First of all, Mr. Turkstra has invited
23 all parties to comment on the exhibit list and
24 transcript excerpts that he's provided to people. We
25 have not responded to Mr. Turkstra.

1 We have no difficulty with the material
2 that has been provided and it was always our
3 understanding as a result of discussions at our initial
4 meeting in June that what we would receive next would
5 be preparation of a witness statement that would be
6 circulated and, as has been the procedure in the past,
7 parties would then file a statement of issues if they
8 wished the right to cross-examine this witness.

9 I just wanted to be clear when we were
10 discussing the statement of issues that that, as has
11 been the normal course, would be something that would
12 happen after parties had an opportunity to review the
13 witness statement with their client.

14 THE CHAIRMAN: That would be correct.

15 MS. SEABORN: And the only other
16 submission I have is that it's our client's position
17 that Dean Baskerville should be here once; i.e., he
18 should not be recalled.

19 THE CHAIRMAN: And you have no objections
20 I take it for his appearing at the end of the
21 Ministry's case?

22 MS. SEABORN: No, that is fine. And I
23 agree with Mr. Cassidy's submissions as to fairness in
24 that regard.

25 THE CHAIRMAN: Any other parties wish to

1 address these issues before we retire for a short
2 break?

3 (no response)

4 Mr. Turkstra?

5 MR. TURKSTRA: I would like, if I could,
6 to clarify one thing, Mr. Chairman. The list of
7 subject matters that we had prepared was intended to be
8 a list of what we construed to be included within the
9 terms of your order.

10 And, for example, Mr. Freidin raises the
11 term--

12 MR. FREIDIN: Habitat supply analysis.

13 MR. TURKSTRA: --habitat supply analysis,
14 thank you. I don't recall that specifically as a
15 subject matter and I'm going to assume for a minute
16 that it is not included, what he means is not included
17 in Section 6 of my outline which is integrated
18 management for habitat and timber.

19 But if it's not there, then it was my
20 position that I was trying to draft a table of contents
21 to the witness statement based on the transcripts and
22 the exhibits. That was a table of contents of the
23 subject matters that came within your order; that is,
24 essentially the audit that had been referred to in
25 these proceedings.

1 And it was my position that if there was
2 a subject matter beyond that that any parties wanted to
3 have included in his evidence, they would have to come
4 back to the Board and say: Well, habitat -- Mr.
5 Freidin, I am sorry, but you will have to give it to me
6 again.

7 MR. FREIDIN: Habitat supply analysis.

8 MR. TURKSTRA: Habitat supply analysis
9 is a subject matter that he should testify on and while
10 it's not directly in the audit we feel that important,
11 and then I would go to work on preparing him on that.

12 THE CHAIRMAN: That would likely be
13 raised in the statement of issues submitted by the
14 other parties.

15 MR. TURKSTRA: All right. But I just
16 don't want to have a misunderstanding that we are in
17 some way informally going beyond the scope of your
18 record.

19 I want to make it very clear that my
20 understanding of what I'm doing is I'm interpreting
21 your order, staying within the scope of that order and
22 I will try and draft a witness statement that meets
23 with that and that all parties have in this document my
24 best interpretation of that order.

25 If there are subject matters which other

1 parties want Dr. Baskerville to testify on that are not
2 included in this list, then it would be my view that
3 they should come back and ask the Board to amend its
4 order of March the 6th.

5 What I'm saying is that I don't want to
6 be put in the position, nor should I be put in the
7 position of unofficially amending your order by
8 expanding his witness statement in response to
9 questions posed.

10 THE CHAIRMAN: No. I think we have to
11 put some bounds on his evidence, so the bounds we put
12 on the evidence in the first instance were dealing with
13 the audit, the collateral documentation or ancillary
14 documentation to the audit and the response and
15 ancillary documentation to the response.

16 Now, should the other parties wish to
17 address other issues they would raise them in their
18 statements of issue and the Board would then in effect
19 rule on those statements of issue as to whether or not
20 those subject matters were relevant to this examination
21 and, if relevant, would be included and, therefore, you
22 would prepare Dr. Baskerville for questions on those
23 other issues and, in that way, we would be able to
24 accommodate, to some extent, the particular concerns of
25 various parties and they would indicate those concerns

1 through their statements of issue.

2 MR. HANNA: Mr. Chairman, if I might just
3 mention, I can see a potential bottleneck coming that
4 the witness statement might be prepared, the statement
5 of issues are then submitted, statements of issue
6 saying: Well, this issue wasn't covered in the witness
7 statement because of Mr. Turkstra's I think quite fair
8 interpretation of the Board's order, then you have to
9 go back to the witness statement.

10 I'm wondering if it isn't somewhat
11 contrary to our normal procedure that some of those
12 issues might not be more properly brought forward at
13 this time and I think Mr. Freidin has made a good
14 example of that, the habitat supply analysis.

15 THE CHAIRMAN: Well, it's difficult for
16 some parties to operate in the abstract. The normal
17 process, Mr. Hanna, has been for the parties to in
18 effect be responding to a statement of issue -- to a
19 witness statement and if they see that what is in the
20 witness statement doesn't cover their concern or
21 doesn't cover an issue they wish to address, they come
22 forward with a statement of issues and we would then
23 have a session whereby those statement of issues which
24 have been distributed amongst all the parties would
25 provide the parties with an opportunity to speak to

1 them and at that time we would rule on whether or not
2 they are relevant.

3 Does that pose any difficulty for you,
4 Mr. Turkstra?

5 MR. TURKSTRA: No, sir.

6 THE CHAIRMAN: Anybody else want to
7 comment before we retire?

8 (no response)

9 And when we come back, Mr. Hanna, we want
10 you to be able to give us some comments on what has
11 taken place to the extent that you will be indicating
12 clearly that if the examination of Dean Baskerville
13 goes as we have discussed, you will not be calling him
14 as a witness.

15 In other words, we are not going to
16 proceed with this if a party is still indicating that
17 they are going to call Dean Baskerville as a witness
18 and, in that case, we would want an undertaking from
19 that party that they will in fact call him. We can at
20 least settle that today.

21 Mr. Turkstra, perhaps during the break
22 you could be available to consult with any of the
23 parties over what has transpired so that when we come
24 back we will have a clear understanding of what the
25 scope of Dean Baskerville's examination will be?

1 Okay. I think we will break for 20
2 minutes. Thank you.

3 ---Recess taken at 2:05 p.m.

4 ---On resuming at 2:30 p.m.

5 THE CHAIRMAN: Thank you. Be seated.
6 Mr. Hanna?

7 MR. HANNA: Mr. Chairman, I have had a
8 chance to speak with the Federation. It appears at
9 this time that the concerns that we had in terms of
10 certain issues that we wished Dr. Baskerville to deal
11 with have been addressed, and we appreciate and accept
12 the suggestion that you made that each party be
13 permitted to prepare a statement of issues and topics
14 by their choice and that they would be then provided in
15 terms of relevancy to the hearing.

16 As a result, on behalf of the Federation,
17 I undertake not to call Dr. Baskerville, subsequent to
18 his appearance as the Board's witness subject to the
19 provisions of his appearance as discussed and they are;
20 namely, the preparation of a witness statement,
21 followed by the issuance of statements of issues by all
22 parties, and the subsequent determination of those
23 issues in terms of relevancy by the Board through a
24 scoping session.

25 THE CHAIRMAN: Very well. Now, just

1 before the Board reiterates what its understanding of
2 all of this is, so that it is quite clear amongst all
3 parties, we would like to get some indication of the
4 timing that might be involved.

5 Mr. Turkstra, can you give us any
6 indication as to when you might have a witness
7 statement prepared with respect to these matters?

8 (microphone feedback)

9 MR. TURKSTRA: Oh, I'm sorry, I thought
10 they fixed it over the break. The last time I will
11 touch it, sir, I will never touch it again no matter
12 what happens whether you can hear me or you can't. I
13 will try it again.

14 What we basically agreed to was that by
15 the end of next week I am to have from all of the
16 parties their comments on the list that Ms. Valiante
17 and I prepared as to what we see the table of contents
18 of Dr. Baskerville's witness statement.

19 The minute I have that in final form it
20 will go to Dr. Baskerville, but bear in mind that that
21 will probably not be until the afternoon of the 15th.
22 He and I then have to get together, I have to get the
23 transcripts to him. Some of this I can work on in
24 advance because I think we are pretty well home free on
25 most of this. I am going to get going on that as a

1 matter of fact tomorrow now that I know that there is
2 no question about who is calling him. And I am hoping
3 to have a draft witness statement, I would hope, by the
4 end of the first week of September.

5 Now, that's pushing Dr. Baskerville, and
6 I say that without having been able to cover this
7 schedule with him, but subject to any problems we have
8 I would hope to have a draft witness statement by the
9 end of the first week of September, and presumably it
10 shouldn't take more than a couple of weeks to get a
11 statement of issues back from the parties on that so
12 that if there is any ruling to be done by the Board
13 that might be done in the latter part of September or
14 the first part of October.

15 Now, that's a -- can I call that a
16 hopeful schedule, sir--

17 THE CHAIRMAN: Okay.

18 MR. TURKSTRA: --as opposed to any kind
19 of assurances?

20 THE CHAIRMAN: All right. But I think we
21 should all be working towards having the statements of
22 issues in from all the other parties in response to the
23 witness statement by the end of September, and then we
24 would hold a scoping session on that very early in
25 October so that the end result of the scoping session

1 would be the issues which Dean Baskerville might be
2 expected to address and then you can instruct him, Mr.
3 Turkstra, on those issues and then he would appear
4 whenever he can be scheduled at the end of the
5 Ministry's case.

6 Now, it is the Board's understanding,
7 therefore, that the earlier ruling will in effect
8 stand, that the Board will call Dean Baskerville as its
9 witness. He will be dealing with the issues identified
10 by Mr. Turkstra as a result of his putting forward the
11 material to the other parties and that will comprise
12 ultimately a draft witness statement to which all
13 parties will respond by way of filing a statement of
14 issues.

15 The Board will then hold a scoping
16 session on the statement of issues and determine which
17 additional issues to those contained in the witness
18 statement will or will not be addressed by Dean
19 Baskerville.

20 Any documents that are going to be dealt
21 with as a result of any further issues identified by
22 the other parties should be identified in the
23 statements of issue because the Board will not want to
24 entertain requests when Dean Baskerville is here to
25 have him address any other documents other than those

1 that have been identified in fairness to him and in
2 fairness to the proceeding in general so as to not
3 prolong it unduly.

4 We will then work towards the schedule
5 that I have just outlined. Hopefully by the end of the
6 first week of October, beginning of the second week of
7 October we will have identified through a scoping
8 session all of the issues to be identified and
9 addressed by Dean Baskerville.

10 Now, as to location of calling Dean
11 Baskerville, there appears to be I think a general
12 consensus that he should probably be called in Toronto.

13 Do any parties have any objections to
14 that course of action?

15 (no response)

16 Very well.

17 Mr. Hanna?

18 MR. HANNA: I think we should just note
19 Mr. Edwards is not here, Mr. Chairman.

20 THE CHAIRMAN: That is true, but I -- was
21 this canvassed at all, Mr. Turkstra, as to where he
22 might be called at the last session you had?

23 MR. CASSIDY: To assist, I think it was a
24 matter of the parties agreed at the time to let the
25 Board make that decision and I think that's what it's

1 doing today.

2 THE CHAIRMAN: Okay. Well, the Board
3 rarely gets such a magnanimous opportunity at the
4 request of the parties and, therefore, we shall make
5 the decision that Dean Baskerville will be appearing
6 before the Board in Toronto at the relevant time.

7 Okay. Ms. Murphy?

8 Are you ready to go on with your
9 witnesses?

10 MS. MURPHY: Yes, we are ready to go.

11 THE CHAIRMAN: Okay. Well, just before
12 you go, one more matter and that is the scoping session
13 with respect to Panel 15. I believe the statements of
14 issue with respect to that panel are due today; is that
15 correct?

16 MR. CASSIDY: I understand that's the
17 Board's ruling. I don't know why I have to get up and
18 do all this.

19 MS. CRONK: I didn't know.

20 MR. CASSIDY: I didn't mean you, Ms.
21 Cronk, my other colleagues who surely read the mail.
22 But, in any event, my understanding from your order is
23 that today was the deadline and I can speak to my
24 colleague Mr. Cosman, I'm sure he can confirm that, but
25 I understood today was the date.

1 And if I could just go back -- bring you
2 back to the matter of Dean Baskerville one more time,
3 am I correct that your intention is to call him as a
4 witness at the conclusion of MNR's case?

5 THE CHAIRMAN: That's correct.

6 MR. CASSIDY: Thank you.

7 MS. MURPHY: Well, I am not entirely
8 sure, but I don't believe we have received any yet and
9 if we have, it has only been one statement of issue.

10 THE CHAIRMAN: Okay. Well, obviously
11 because of the break the parties maybe lost track of
12 where we are or where we were and, under those
13 circumstances, we can extend the date for submission.

14 They should be in I think by the end of
15 this week so that we can have a scoping session
16 possibly towards the end of the following week for 15.
17 So that will allow sufficient time for counsel to
18 prepare the witnesses who I guess will be called some
19 time in early October.

20 Is that the present plan?

21 MR. FREIDIN: Oh no, no. I think the
22 present time it could be as early as September the
23 11th, the way we calculated our time.

24 THE CHAIRMAN: Okay. So you will
25 definitely have direct in prior to us breaking for the

1 Dryden session; is that correct?

2 MR. FREIDIN: By September the 11th,
3 that's correct.

4 THE CHAIRMAN: Okay.

5 MS. SEABORN: Could we set a time today,
6 Mr. Chairman? There may be other counsel who would be
7 interested in being here for the scoping session of
8 Panel 15.

9 THE CHAIRMAN: All right.

10 MR. FREIDIN: Mr. Chairman, I have got a
11 little bit of a problem with the end of next week. If
12 it is agreeable to the Board and to other people,
13 Monday -- if we are sitting Monday, August the 21st, it
14 would be preferable for the scoping session -- sorry,
15 the 22nd, Tuesday the 22nd, as opposed to the end of
16 next week.

17 THE CHAIRMAN: All right. This scoping
18 session may be a little lengthier than some of them
19 because of the subject matter of Panel 15. It may be a
20 rather lengthy panel and there may be a number of
21 issues that have been held over from other panels.

22 So I think if we set it for Monday the --
23 sorry, Tuesday the 22nd, we might as well do it when we
24 commence at 1:00 p.m. on the Tuesday.

25 Mr. Turkstra?

1 MR. TURKSTRA: I just wondered if I might
2 be excused.

3 THE CHAIRMAN: Yes. I don't think Mr.
4 Turkstra need wait around any longer now that we have
5 settled the matters with Dean Baskerville.

6 Thank you for your attendance. If you
7 move it you may get out on the 4:40 or 4:50.

8 MR. TURKSTRA: Thank you very much.

9 THE CHAIRMAN: Ms. Murphy?

10 MS. MURPHY: Thank you. If I could ask
11 Dr. Ritter and Mr. Kingsbury to come up and take their
12 places.

13 THE CHAIRMAN: Perhaps we might swear
14 them, Ms. Murphy?

15 MS. MURPHY: Yes. And I understand that
16 Dr. Ritter would prefer to affirm, sir.

17 THE CHAIRMAN: Very well. Mr. Kingsbury,
18 would you step forward, please.

19 PETER KINGSBURY, Sworn
20 LEONARD RITTER, Affirmed

21 MS. MURPHY: This is, as you know, the
22 recommencement of the second part of Panels 12 and 13,
23 and before I make my opening remarks I would like to
24 take the opportunity to file a number of exhibits and I
25 prefer to file all of the exhibits that we expect to be

1 used by both witnesses at the outset so that we don't
2 need to mark them later.

3 I believe we are at Exhibit 707, that was
4 my understanding. Is that correct, sir?

5 THE CHAIRMAN: Yes, that is correct.

6 MS. MURPHY: Then the first document I
7 have is the supplement to the curriculum vitae of Peter
8 Kingsbury and I propose that that be marked as Exhibit
9 707.

10 THE CHAIRMAN: Very well. Exhibit 707.

11 ---EXHIBIT NO. 707: Supplement to curriculum vitae
12 of Peter Kingsbury.

13 MS. MURPHY: And I am also providing a
14 curriculum vitae for Leonard Ritter which I propose be
15 Exhibit 708.

16 THE CHAIRMAN: Very well.

17 MS. MURPHY: And both of these documents
18 have been provided to my friends previously.

19 ---EXHIBIT NO. 708: Curriculum Vitae of Leonard
20 Ritter.

21 MS. MURPHY: Now, with reference to the
22 evidence of Dr. Ritter, I have a package of -
23 (microphone feedback) - I have hard copy of a series of
24 slides that will be referred to by Dr. Ritter.

25 In fact, what I am going to be giving you

1 is two packages. One is a series of overheads, the
2 pages are numbered -- in the one that will be the
3 exhibit I have marked the pages A to J, and Dr. Ritter
4 will also be showing a few slides and I am going to
5 give you those separately.

6 So I would suggest that the overheads be
7 marked Exhibit 709, pages A to J.

8 THE CHAIRMAN: Okay. Hard copies of
9 overheads, Exhibit 709, numbered A through J.

10 ---EXHIBIT NO. 709: Hard copy of series of slides
11 numbered A through J.

12 MS. MURPHY: And with respect to the
13 photographs, I have prints of the photographs and also
14 some photocopies and I would suggest then that that be
15 Exhibit 710, numbers 1 to 5.

16 There are numbers on the back of the
17 photographs, and we will have to ask Dr. Ritter to
18 identify and describe the photographs as he puts in his
19 evidence.

20 THE CHAIRMAN: Very well.

21 ---EXHIBIT NO. 710: Prints of photographs numbered 1
22 through 5 to be referred to by Dr.
Ritter in evidence-in-chief.

23 MS. MURPHY: And with respect to the
24 evidence of Mr. Kingsbury, I have two exhibits to file.
25 One is a series of overheads. I have marked the

1 exhibit pages A to D, there are four pages, and I would
2 suggest that that be Exhibit 711.

3 THE CHAIRMAN: Very well.

4 ---EXHIBIT NO. 711: Hard copy of series of overheads
5 numbered A through D to be
6 referred to by Mr. Kingsbury
in evidence-in-chief.

7 MS. MURPHY: And finally what I would
8 suggest be Exhibit 712 is an article that Mr. Kingsbury
9 will be referring to entitled: Pesticides in Forestry
10 and Agriculture, Effects on Aquatic Habitats with a
11 series of authors. It is probably easiest for us to
12 cite it as Kingsbury, et al.

13 ---EXHIBIT NO. 712: Article entitled: Pesticides in
14 Forestry and Agriculture, Effects
15 on Aquatic Habitats authored by
Kingsbury, et al.

16 MS. MURPHY: And also before I begin my
17 remarks, I would like to introduce to you a Deborah
18 Prupas. She is a lawyer from the Department of Justice
19 and I thought it would be nice for people to know who
20 she was. This is her first visit to the hearing.

21 THE CHAIRMAN: Thank you. How do you
22 spell her last name?

23 MS. MURPHY: P-r-u-p-a-s, I believe.

24 THE CHAIRMAN: Thank you.

25 MS. MURPHY: As you know this is a

1 continuation then of Panels 12 and 13. The panel as a
2 whole deals with maintenance of the forest and includes
3 tending and protection. Certain of those activities
4 involve the use of pesticides and you will also recall
5 from Panel 11 that certain aspects of regeneration
6 activities can also involve the use of pesticides, in
7 particular herbicides.

8 Mr. Kingsbury was originally intended to
9 appear together with Panels 12 and 13 in that group and
10 of course, as you understood, his commitments didn't
11 allow him to do that, so we had arranged for him to
12 appear at this time.

13 Given certain comments from the Board
14 during the motion brought by Forests for Tomorrow and
15 in your Reasons for Decision, the Ministry of Natural
16 Resources understood that the Board would like to have
17 further information about the federal registration
18 process, and we have invited Dr. Ritter here to speak
19 to you on that.

20 And you had also advised that it would be
21 preferable in your view, and certainly was in the view
22 of others, to have both witnesses appear together.

23 Dr. Ritter has gone to a fair bit of
24 difficulty to clear his time to be here with us
25 together and we would like to thank him for that. We

1 were also concerned about the time, but I think people
2 have already advised us about how much time they think
3 they will be and that's very helpful.

4 Dr. Ritter had another -- a couple of
5 other matters he wanted me to raise with you and I will
6 leave that towards the end. I just have a couple of
7 general comments to make first.

8 As you know, it is our view that it is
9 most important for the Board to understand the
10 processes that limit the potential for adverse human
11 health effects. The important aspects of those
12 processes are the federal regulation of pesticides
13 under the Pest Control Products Act, provincial
14 approval and permitting systems which deal with
15 individual projects in forestry; that, of course, is
16 administered by the Ministry of the Environment; and
17 further safeguards which are provided through documents
18 such as MNR's manuals and guidelines for field
19 applications.

20 Now, you have heard some evidence about
21 all of these matters, you will be provided further
22 information about the federal regulatory process by
23 this part of the panel. Dr. Ritter will describe first
24 the federal regulatory process and, in particular, the
25 input of Health and Welfare Canada in that process.

1 The second matter he will discuss is the
2 data requirements for toxicity assessments; next, Dr.
3 Ritter will explain exposure assessment; and, finally,
4 he will deal with risk assessment as it relates to
5 human health.

6 Now, with respect to potential effects of
7 registered pesticides on other aspects of the natural
8 environment, as we advised earlier, the Ministry of
9 Natural Resources believes that the situation is a
10 little different. The products discussed are intended
11 to affect certain parts of that natural environment and
12 in so doing have potential to affect others.

13 That being the case, it was our view that
14 the Board should be provided with the best information
15 possible on the potential effects of these products on
16 those aspects of the natural environment most likely to
17 be affected. In attempting to do this we were looking
18 at basically two problems that we had.

19 The first one is that I am advised, and I
20 am sure these witnesses will be able to tell you, that
21 there is tremendous literature that deals with these
22 matters and we wanted to find a way to provide a
23 concise summary, relevant information without having to
24 enter literally hundreds of reports, reviews, et
25 cetera.

1 The second problem was that people who
2 tend to deal with these matters on a daily basis tend
3 also to have fairly specific focus, and we were
4 concerned that if we were to provide witnesses with
5 specific expertise in each and every aspect of the
6 matters that could be raised that would involve many,
7 many people.

8 So in attempting to deal with those
9 problems, as you are aware, we have taken the approach
10 of using the process that is facilitated by the ESSA
11 group and have produced that document that you have,
12 Document 4, which is Exhibit 604C, I believe.

13 You will recall that the methodology was
14 described by Dr. Kingsbury -- Dr. McNamee actually in
15 Panel 8 at some length. The methodology involves
16 obtaining input from a cross-section of experts
17 initially at a working session in which the experts
18 prepare draft reports. The drafts are subsequently
19 reviewed by workshop participants and, in this
20 particular case, the draft was subsequently reviewed by
21 a second group of experts, an outside peer review.

22 The authors of each section of the report
23 are listed on page 6 and the outside reviewers are
24 listed on page 7 of the document. The end result is a
25 concise summary of relevant information. The document

1 sets out the framework for analysis, the conclusions of
2 the experts and the information used to arrive at the
3 conclusions and that document has been subject to peer
4 review.

5 With respect to this information, the
6 person we are calling is Mr. Peter Kingsbury and Mr.
7 Kingsbury will discuss the following topics:

8 First, he will discuss the federal
9 regulatory system and post-registration research with
10 particular emphasis on aspects that deal with the
11 generation and evaluation of environmental toxicology
12 studies related to forestry pesticide use. That's the
13 generation and evaluation of environmental toxicology
14 studies related to forestry pesticide use.

15 Secondly, he will describe the principles
16 involved in assessment of potential environmental
17 effects and in doing that will explain how such
18 assessments are organized.

19 And finally he will discuss the use of
20 information such as that found in the ESSA Document and
21 he will take us to the conclusions reached by the
22 participants in the ESSA exercise and comment on the
23 conclusions.

24 Now, as I advised a little earlier, Dr.
25 Ritter did ask me to mention a couple of things to the

1 Board before we begin, and this will would just make a
2 minute, but you will recall you were advised during
3 argument on the motion brought by Forests for Tomorrow
4 that there is currently underway a legislative review
5 of the federal regulatory system. That group is called
6 the Pesticide Registration Review. It is headed by a
7 gentleman called Ghislain LeBlond and he was appointed
8 by the Prime Minister's office.

9 This committee includes representation
10 from a number of interested persons and will invite
11 submissions from the public. It is anticipated that
12 the review will take many months and will result in a
13 report and recommendations to the federal government.

14 Now, the reason that Dr. Ritter wanted
15 that mentioned is that he would like you to understand
16 that he is discussing the federal regulatory system
17 obviously as it exists now and that he cannot
18 anticipate, of course, the results of the deliberations
19 of that committee or of the federal government upon
20 release of that report, and he feels it would be
21 improper for him to do so. And I am sure you will
22 understand the situation, but I thought it wise to
23 raise it with you at this time.

24 The second matter, of course, Dr. Ritter
25 was asked to appear here fairly recently. He has not

1 had the opportunity to review all of the open
2 literature that exists with respect to specific
3 products. He advises it would take many months to do
4 that and we certainly have not asked him to do that.

5 As you are aware, it is our position that
6 the focus here should be on the regulatory process
7 itself. But, in any event, Dr. Ritter would like you
8 to understand that as a practical matter he may well be
9 limited if one looks at specific information, given
10 that he hasn't done a specific review of all
11 information that exists at this point in time.

12 As a related matter and one that, of
13 course, has come up before is that some of the
14 information that does exist is information that belongs
15 to third parties.

16 Now, at this point we don't know whether
17 anyone will ask Dr. Ritter about that kind of
18 information or whether anyone will ask the Board to
19 make orders with respect to that kind of information.
20 I just thought at this point it would be wise to
21 mention this and to point out that if this kind of
22 situation arises we may be in a situation of asking the
23 Board to consider whether notice should be given to
24 other parties that may have an interest in whether that
25 information be produced.

1 THE CHAIRMAN: I take it this is
2 information of a proprietary nature?

3 MS. MURPHY: Yes, sir.

4 And finally, Dr. Ritter commonly goes to
5 public meetings and so forth and explains how his
6 department functions and what they do, and he would
7 like you to know that he's here in the same role as a
8 public servant advising about what he does and he's
9 prepared to do that. He's interested in assisting the
10 Board and the other parties in understanding what he
11 does.

12 And, therefore, we would ask that Leonard
13 Ritter, based on the information that has been provided
14 to the parties, the updated and completed CV -- of
15 course Dr. Ritter's entire CV, we would submit that Dr.
16 Ritter is an expert in toxicology and the work of
17 Health and Welfare Canada in the regulation of
18 pesticides in Canada and would ask him to be so
19 qualified.

20 THE CHAIRMAN: Any objection by anyone?

21 (no response)

22 Very well, be so qualified. Thank you.

23 MS. MURPHY: And Mr. Peter Kingsbury is
24 an expert in the environmental effects of pesticides
25 used for timber management and, in particular, in the

1 execution and evaluation of scientific investigations
2 about those effects.

3 THE CHAIRMAN: Any objections?

4 (no response)

5 Qualified in those areas.

6 MS. MURPHY: Thank you. And at this
7 point I think I will just ask Dr. Ritter to commence.

8 DIRECT EXAMINATION BY MS. MURPHY:

9 Q. And you can have your machine ready.

10 DR. RITTER: A. All right, I'm all set.
11 Is this on or off? We're off and away.

12 Q. I think so.

13 A. Mr. Chairman, in preparing for my
14 presentation here today we felt that --

15 THE CHAIRMAN: Can everyone hear?

16 MS. CRONK: Not very well, sir.

17 DR. RITTER: Is that better?

18 THE CHAIRMAN: Yes.

19 DR. RITTER: In preparing for my
20 appearance, Mr. Chairman, before the Board we felt that
21 the most expedient way in which to present the
22 information which I intend to present was in the form
23 of a quasi-formal presentation.

24 With your permission I would like to
25 proceed on that basis and take perhaps 35 or 40 minutes

1 to tell you a little bit about the process involved in
2 the regulation of pesticides, specifically the role of
3 the Department of National Health and Welfare.

4 I'm anxious to answer any questions which
5 you might have or clarify any confusion that I may
6 create during the course of the presentation.

7 Frequently we find though that some of the confusion is
8 in fact clarified in a fuller context of the
9 presentation, so I leave it to your discretion. Either
10 way is fine by me.

11 THE CHAIRMAN: Ms. Murphy, we are going
12 to proceed formally in that the other parties will have
13 an opportunity to cross-examine at the appropriate
14 time?

15 MS. MURPHY: Oh yes, that's fine. It's
16 easier for Dr. Ritter to simply put in his evidence in
17 the way he's used to doing it, so we thought it would
18 be easier for him.

19 THE CHAIRMAN: Very well.

20 DR. RITTER: I wonder if I could just
21 stand while I do this because I can see the Board
22 better from here. We are going to need the lights out
23 over here if I can. Thank you.

24 Pesticides are regulated in Canada under
25 federal statute. The piece of legislation which

1 governs the regulation of pesticides is the Pest
2 Control Products Act. What I would like to do
3 initially is to show you the routing of a pesticide
4 submission as far as those regulations are concerned.

5 As I mentioned, the pivotal piece of
6 legislation is the Pest Control Products Act for which
7 legislative authority resides with the Minister of
8 Agriculture. So submissions to register a new
9 pesticide in Canada or for expansion of an existing
10 registration are made to the Department of Agriculture.

11 The Department of Agriculture in turn
12 calls on a variety of agencies...

13 THE CHAIRMAN: Dr. Ritter, could we ask
14 you to slow down a little bit because the court
15 reporter has to take down every word.

16 DR. RITTER: I'm sorry, I will.

17 THE CHAIRMAN: Thank you.

18 DR. RITTER: The Department of
19 Agriculture in turn calls on a number of other agencies
20 and other departments within the federal network to
21 carry out its work and I would like to spend a few
22 moments reviewing the responsibilities of these various
23 departments.

24 First is Health and Welfare, the
25 department that I represent here, and I'm going to have

1 a little more to say about that in a moment, so I'm
2 going to leave it.

3 The Canada Department of the Environment
4 is responsible for assessing essentially environmental
5 impact associated with pesticide use. Department of
6 Fisheries and Oceans, as the name would imply, is
7 responsible for the assessment of potential impacts on
8 aquatic habitats associated with pesticide use and
9 frequently are involved in review of petitions where
10 the use of a product may impact on aquatic environment.

11 Department of Agriculture itself is
12 involved in reviewing the efficacy of the product. In
13 contrast to regulations set out in the United States by
14 the Environmental Protection Agency, in Canada a
15 product must be shown to work before it can be
16 registered. That is, as I mentioned, in contrast to
17 what appears in the United States because in fact the
18 requirement for the product to work doesn't exist
19 within EPA regulations. The Americans take the view
20 that the marketplace will determine the value of the
21 product and that need not be entrenched in regulation.

22 The Department of Forestry, which is a
23 relatively new department although previously carried
24 out its mandate under the Department of Agriculture, is
25 involved in pesticide submissions involving the

1 application to forests. They will be involved in a
2 variety of studies which may include environmental
3 impact, aquatic impact and also on the efficacy of
4 pesticide used within the forestry sector.

5 The department, as you know, which I
6 represent principally is the Department of Health and
7 Welfare. I would like to tell you a little bit about
8 the responsibilities of that department and how these
9 responsibilities are divided up internally.

10 Organizational within the Department of
11 National Health and Welfare, the umbrella organization
12 is the Health Protection Branch and among other
13 activities there are two directorates within the Health
14 Protection Branch that are concerned with the
15 registration and use of pesticides.

16 One is the Food Directorate. The Food
17 Directorate is concerned with the use of pesticides in
18 that they may find their way into foods which will
19 subsequently be sold and consumed by Canadians as well
20 as for export. To carry out their responsibilities the
21 Food Directorate is responsible for what we call
22 establishment of maximum residue limits or, in other
23 words, the Food Directorate is responsible for
24 establishing the maximum quantity of a pesticide
25 residue which may be present lawfully in the food at

1 time of consumption.

2 The other group within the Health
3 Protection Branch that is interested in the use of
4 pesticides is the Environmental Health Directorate,
5 that is the group that I represent.

6 The Environmental Health Directorate has
7 two interests in the use of pesticides. One relates to
8 the assessment of the presence of pesticides in
9 Canadian drinking water and although the establishment
10 of guidelines for contaminants in drinking water is
11 provincial jurisdiction, recommendations for maximum
12 limits which may be permitted in water are established
13 on the basis of a consultation process in which the
14 federal and provincial departments both play a role.

15 Ultimately these consultations lead to
16 establishment of what I have referred to here as the
17 national drinking water guidelines which frequently, if
18 indeed not all the time, are implemented as lawful
19 limits by the various provincial regulatory agencies.

20 The second responsibility of the
21 Environmental Health Directorate and the one with which
22 I will spend the most time this afternoon is the
23 assessment of worker and what we refer to as bystander
24 exposure during the routine use of pesticides in many
25 various applications in which they can be used.

1 I'm going to spend the next three or four
2 slides going through the kinds of toxicology studies
3 that we require and I'm going to take a moment or two
4 as we go through them to explain the scientific logic
5 behind them and the kind of information that they
6 provide.

7 The simplest studies that we require both
8 in terms of their complexity and in terms of their cost
9 are what we refer to as acute toxicity studies. By
10 definition acute studies tend to be those studies which
11 look at potential effects following the single usually
12 high dose exposure to the chemical.

13 These studies are carried out on both the
14 active ingredient and the formulated product and these
15 two are very different commodities. By way of example
16 there is approximately 450 active ingredients in Canada
17 but roughly 5,000 registered products.

18 Acute studies, as I mentioned, are
19 required on both the active ingredient alone as well as
20 the total product which is sold at the retail level
21 containing that active ingredient.

22 The studies that we require of these two
23 components, as I mentioned, are these acute toxicity
24 studies and they will include what we call the lethal
25 median dose study or the LD50.

1 This is a study which is designed to tell
2 us a little bit about the dose that is required to
3 achieve death in 50 per cent of the test population.
4 And to assure that there is not significant differences
5 in the sensitivity as a function of route, these
6 studies typically are carried out following oral
7 ingestion, following application to the skin, and
8 following inhalation.

9 Now, there are circumstances where any of
10 these studies may be waived if toxicologically they are
11 considered to be inappropriate. For example, it would
12 be pointless to carry out an inhalation study on a
13 product which is sold and used as a solid.

14 This is generally a matter of judgment
15 and often a matter of liberation between the petitioner
16 and the Health Protection Branch.

17 THE CHAIRMAN: Are all of these studies
18 vis-a-vis humans or any of them?

19 DR. RITTER: No, none of these studies
20 are in humans. The studies are carried out typically
21 in rodents generally speaking but are frequently
22 carried out in non-rodent species as well.

23 In the case of the LD50 study, for
24 example, the majority would be carried out in rodents,
25 but frequently these studies are also carried out in

1 such animals as rabbits, sometimes higher primates.

2 These studies -- I should say in answer
3 to that question, Mr. Chairman, the situation in Canada
4 is pre-market; that is, all products which we will be
5 discussing must undergo this testing scheme before they
6 can be registered. Because these agents are not
7 therapeutic and are not intended for human use, indeed
8 not even for human contact, the objective of course is
9 to avoid human contact and consequently are never
10 tested in humans.

11 The second series of --

12 MR. MARTEL: Can I ask a question?

13 DR. RITTER: I'm sorry.

14 MR. MARTEL: Did you say all these
15 products were pre-market tested?

16 DR. RITTER: That's correct, when I'm
17 referring to the public health aspects. Canada is a
18 pre-market test organization unlike many of our
19 European counterparts where the bulk of the testing may
20 be carried out once the product has been introduced
21 into the market. All of the toxicological studies that
22 I will give you -- that I will describe must be carried
23 out prior to registration of the product.

24 The second series of studies which we see
25 in this acute package are irritation: dermal and eye.

1 Irritation studies as the name implies tell us a little
2 bit something about the potential of a chemical to
3 cause an irritant effect. And as the case of the LD50
4 study, these studies are carried out typically on the
5 active ingredient and on the product. They are carried
6 out by application both to the skin and to the eye.

7 I'm sure many of you are aware that the
8 use of eye irritancy studies has fallen out of favour
9 in the last few years and many animal rights groups
10 feel that this is an inappropriate study to carry out.

11 We share that conviction and, generally
12 speaking, if a chemical or its formulated product is
13 considered to be a skin irritant, we will generally be
14 prepared to waive the requirement for an eye irritancy
15 study provided that the petitioner is prepared to
16 concede that it is likely to be an eye irritant.

17 The third group of these short-term
18 studies that we require is sensitization and to put it
19 another way that is simply a series of studies that
20 tell us a little bit about the potential of the
21 chemical to cause allergic effects. Once again these
22 studies are typically carried out on the active
23 ingredient and on the formulated product as it's sold
24 commercially.

25 THE CHAIRMAN: Can we ask you again to

1 try and slow down a little bit. I know it's difficult,
2 but we have to take notes and the court reporter has to
3 take notes as well.

4 DR. RITTER: I apologize again.

5 MS. MURPHY: I'm concerned whether I
6 should try turning that up again just a little bit. We
7 can give it a try and see if we have major
8 difficulties. What do you think? I will give it a
9 try.

10 THE CHAIRMAN: Okay.

11 MS. MURPHY: I will turn it back down if
12 it doesn't work.

13 DR. RITTER: Okay. I'm going to do my
14 best to slow down once again and I apologize again.

15 Sensitization, as I indicated, are a
16 series of studies which are intended to tell us a
17 little bit about the potential of the chemical to
18 induce allergic reactions in individuals. Again these
19 studies, as the others, are carried out with both the
20 active ingredient alone as well as the final product in
21 the way in which it is sold.

22 I should mention just out of interest
23 that typically where we see an allergic reaction in
24 association with exposure it is frequently in
25 association with the non-active components of the final

1 product. It is frequently the solvent or emulsifier or
2 some other additive which may be present in the final
3 product but absent in the active ingredient alone.
4 That is anecdotal and not very useful but interesting.

5 Delayed neurotoxicity is a very
6 specialized group of studies. These studies are
7 designed to tell us whether or not a chemical has
8 the potential to induce what we refer to it as a
9 delayed neurotoxic effect.

10 In Canada these studies are required
11 specifically in the group of chemicals that we refer to
12 as the organophosphorous chemical. Historically these
13 chemicals are insecticides and with particular
14 reference to the forestry spray programs these
15 chemicals have often found their way into use in
16 forestry insecticide programs, most notably perhaps in
17 New Brunswick historically in Canada. These studies,
18 as I mentioned, are specifically part of this group of
19 chemistry.

20 MR. MARTEL: Is there a required -- when
21 you are looking at that, do you look at the time in
22 which it might appear; in other words, the latency
23 period?

24 DR. RITTER: I think the best way to
25 answer that is perhaps if I just took a moment to

1 describe very briefly the protocol for this study.

2 This study is done in chickens and it's
3 done in chickens because chickens have a nervous system
4 which is not unlike our own and is rather susceptible
5 to damage.

6 The study typically involves
7 pre-treatment of the test animals with an agent which
8 is designed to protect them from death following
9 exposure to relatively high doses of these chemicals.
10 So these animals are pre-treated with atropine which
11 will protect against death from these agents. They are
12 then exposed and then following a period of time maybe
13 re-exposed once again which is why the study is often
14 referred to as delayed.

15 There is a number of variations on this
16 protocol. The study involves examining these animals
17 both physically for physical symptoms and signs of
18 toxicity as well as histologically; that is, selected
19 areas of the nervous system are dissected out and
20 examined microscopically for damage to the nervous
21 tissue.

22 So in answer to your question yes and
23 yes. The study protocol involves optimizing the
24 opportunity for the effect to express itself both in
25 terms of physical trauma as well as histologic evidence

1 which may not necessarily be apparent on physical
2 examination.

3 The next series of studies that we
4 require are what we refer to as the short-term studies
5 and some might refer to them as sub-chronic, others
6 might use the term sub-acute but they are all intended
7 to impart the same sort of time frame.

8 The first study which we require is the
9 90-day oral study and this is conducted in at least two
10 species. In Canada the most frequent species in which
11 these studies are done are the rat and the dog.

12 These studies are really intended to
13 serve two purposes. The first is that the study
14 provides useful information on the non-acute; that is,
15 exposures which may occur more frequently than once but
16 less than a lifetime. As a reference point in the rat,
17 for example, lifetime is considered to be approximately
18 two years, about 24 months, so that a 90-day study
19 would represent roughly one eighth of the anticipated
20 lifespan of the test animal.

21 These studies incidentally are carried
22 out in two species to minimize the likelihood that any
23 one species is providing incorrect information. I
24 would also ask you to note that where they are
25 conducted in two species typically one of the species

1 is a non-rodent and that is again designed to minimize
2 the opportunity that any one species provides erroneous
3 information. This is particularly for applications
4 involving pesticides which may be applied to food.

5 This is often followed, in Canada is
6 always followed by what we call a 12-month oral dog
7 study and, as the name implies, this is involves
8 dietary administration of the test material to a group
9 of dogs for a period of 12 months. And again, while
10 this is not a lifetime study, it is a study which is
11 intended to provide useful information on the non-acute
12 continuous dietary exposure to the chemical in
13 question.

14 We may and certainly have in the past on
15 occasion requested non-acute or 90-day dermal or
16 inhalation studies on a given active ingredient or a
17 given product. These studies may be required if, in
18 our view, the product represents a unique opportunity
19 for repeated dermal contact and where, in our view,
20 that dermal contact may represent the most significant
21 route of entry and the most significant risk.

22 Similarly we may also require in addition
23 to or instead of that dermal study that a long-term or
24 a non-acute study be conducted by the inhalation route
25 for exactly the same reason. If we feel that

1 inhalation will constitute the major route of exposure
2 and that this may represent a significant risk, we may
3 ask that these studies be conducted by the inhalation
4 route as well.

5 Again there is a variety of additional
6 neurotoxicity studies that we may require for
7 organophosphorous chemicals such as the neurotoxic
8 esterase and others which we will require if the
9 initial studies on neurotoxicity indicate any positive
10 result.

11 The last series of toxicological studies
12 that we require in support of an application are by far
13 and away the most complex and the most expensive. I'm
14 going to give you some dollar figures just to give you
15 a sense of the kind of order that we are talking about
16 over here. The two most complicated studies I suppose
17 that we require are what we refer to as chronic feeding
18 and oncogenicity and in a sense these studies are very
19 similar.

20 In both cases these studies involve
21 dietary administration for at least 90 per cent of the
22 anticipated lifespan of the test animal, dietary
23 administration for at least 90 per cent of the
24 anticipated lifespan of the animal with doses which
25 should be as high as is possible from a practical point

1 of view; that is, the highest dose administered in
2 these studies should be sufficiently high to induce
3 minimal signs of toxicity. And frequently when these
4 studies do not achieve that high dose, these studies at
5 the end of the day may be rejected as not having
6 satisfied the objective of the overall protocol.

7 I mention that because over the years
8 there has been concern and controversy when chemicals
9 such as cyclamates which you may remember a number of
10 years ago were the subject of some poking of fun
11 because there were some who argued that in order for
12 you and I to be exposed to the kinds of doses that
13 these rats got we would have to consume 50,000 cans of
14 diet pop a day.

15 I should emphasize that these studies are
16 not intended to replicate the human anticipated
17 exposure, not intended to replicate human exposure.
18 They are intended to optimize the opportunity for an
19 event to occur and, consequently, the dosing schedule
20 is selected on such a basis so as to provide as much
21 chemical as is possible from a practical point of view
22 to these animals for the longest possible duration.
23 Consequently, we selected the 90 per cent lifespan and
24 the sub-maximal toxic dose for administration to these
25 animals.

1 The primary difference between these two
2 studies -- some of you with some basis in Latin may
3 recognize the term oncogenicity, both of these studies
4 are designed to look at tumors, the ability of a
5 chemical to induce cancer. The primary difference
6 between them is the chronic feeding study does more
7 than just that. While it includes a count of tumors at
8 the end of the exercise, it also includes a rather
9 thorough examination of a variety of other parameters
10 such as the effect of the chemical on a variety of
11 organ systems; liver and lung, so on and so forth. It
12 will look at haematology, effects that the chemical may
13 have on any number of blood parameters, effect on
14 biochemistry, urine analysis, so on and so forth.

15 Oncogenicity studies tend to be rather
16 selective in that they tend to look only at the
17 induction of tumors in association with exposure to the
18 chemical.

19 You see the rats here repeated because
20 indeed these studies are often combined; that is, the
21 oncogenicity and chronic feeding study is done in the
22 rat and the oncogenicity study alone is done in the
23 mouse.

24 The rat incidentally is selected as the
25 species for the chronic feeding study because a rat is

1 much larger, has a larger volume of blood, is more
2 amenable to the kinds of investigations that are done
3 in these studies.

4 The next study that we require is what we
5 call pharmacokinetics and these are a series of studies
6 that are designed to tell us what happens to the
7 chemical once exposure has taken place; that is, how is
8 it absorbed, how do we get rid of it, if we retain it
9 where does it go, what are its metabolites once it gets
10 in, is it changed to something more toxic or less toxic
11 on absorption, so on and so forth. How long is it
12 retained if it's retained. All of these sorts of
13 questions relating to metabolism and pharmacology are
14 generally addressed in the pharmacokinetic studies.

15 I have indicated here by appropriate
16 routes because, as I mentioned earlier on, our primary
17 considerations here today are with worker and bystander
18 exposure. Consequently, it may not necessarily be
19 appropriate to conduct these studies following oral
20 administration which is a convention and we have
21 frequently, for example, required that these studies be
22 conducted following dermal exposure to the chemical
23 which is where we normally see most of the exposure to
24 take place in an occupational study.

25 Mutagenicity is again another Latin

1 derivative and it refers to the capacity of the
2 chemical to induce heritable change, refers to --

3 MS. MURPHY: Q. I'm sorry, produce what?

4 DR. RITTER: A. Heritable change. It
5 really refers to the capacity of the chemical to
6 interact with the genes, with the genetic material of
7 the cell and to in some way alter that genetic
8 material.

9 Teratology looks at the capacity of the
10 chemical to induce birth defects and, like some of the
11 other studies, we require that this study in particular
12 be conducted in at least two species, one of which must
13 be a non-rodent.

14 Multi-generation reproduction study is a
15 study which looks at the capacity of the chemical to
16 induce reproductive disorders other than birth defects
17 because those are, of course, addressed in the
18 teratology studies.

19 And by way of example we mean by
20 reproductive disorders, this study will look at things
21 such as spontaneous abortion rates, resorption rates,
22 the number of live births, the gestational period, has
23 the chemical affected the gestational period in the
24 test species and so on and so forth.

25 MRS. KOVEN: Would you explain what

1 resorption means?

2 DR. RITTER: Pregnancies are not always
3 successful. There is frequently, in fact much more
4 frequently than I think most people realize, the
5 capacity to spontaneously resorb a fertilized egg both
6 in the human situation and experimentally for many,
7 many reasons which I won't go into.

8 One of the things that this study looks
9 at are these resorption sites; in other words, of the
10 number of potential pregnancies, how many actually
11 develop into full-term pregnancy.

12 One tends to use the word -- the term
13 spontaneous abortion for aberrant effects which take
14 place much later in the gestational cycle, whereas the
15 resorption that I'm referring to tends to take place
16 very early on following fertilization, but this study
17 has within its protocol the ability to detect both of
18 those changes.

19 MRS. KOVEN: Excuse me, where do you put
20 birth weight on this --

21 DR. RITTER: Birth weights. Birth
22 weights are actually measured in both but because
23 teratology studies by convention now -- I don't mean to
24 belabour the answer, but I'm going to have to.

25 Animals, as many of you may know,

1 particularly rodents tend to consume their young. Now,
2 many years ago teratology studies usually involved
3 delivery of the young following full-term pregnancy.
4 The difficulty with that was that if you were not there
5 at the exact moment of birth the results could have
6 been somewhat affected. You could come into an
7 examination and find that there were only half as many
8 more than you expected, there may have been all of them
9 to start with and you may have missed some of them.

10 What is done now by convention in
11 teratology studies is these animals are delivered
12 typically about 24 hours by caesarean section prior to
13 a delivery when it can be expected to take place. So
14 that birth measurements are not really all that useful
15 any longer in the teratology protocol.

16 Most of the birth measurements that you
17 are referring to, and I think you are referring to, are
18 now taken in the multi-generation study because, as the
19 name implies, this is multi-generation, each generation
20 becomes the parent of the subsequent generation. So if
21 you think about it there is actually a large number of
22 parameters that are being tested within this protocol.

23 For example, if there is an effect which
24 is associated with the presence of the toxic chemical
25 in breast milk, that chemical will find its way into

1 this lactating process in the multi-generation study,
2 may affect subsequent generations whereas it did not
3 affect the first generation. And we see that from time
4 to time, where there is a toxic effect expressed in the
5 second generation which was not present in the first
6 generation. Often explainable on the basis of the
7 introduction of this chemical in the lactation where it
8 would not have been present in the initial generation
9 that was tested, so on and so forth.

10 The last group of studies are the worker
11 exposure studies and we were the first country in the
12 world to formally require that worker exposure studies
13 be conducted and the first country in the world to
14 formally require them routinely in support of every
15 product registration which we now look at.

16 And while the toxicology that I have
17 described is pretty much standard around the world with
18 most agencies that have toxicology data requirements,
19 the worker exposure studies are somewhat unique to
20 Canada. And although the Environmental Protection
21 Agency in the United States now requires them to some
22 greater or lesser extent, I would like to spend a
23 little bit of time showing you how we do these because,
24 as I say, this is where we have really made our mark
25 internationally.

1 Once the toxicological studies have been
2 completed one can actually determine from that what is
3 an acceptable use. By way of an example - and if you
4 would just imagine because it did not come out in the
5 graphics - there should be a line right through there,
6 so that this equation has a numerator and a
7 denominator.

8 From the toxicological studies that I
9 have described for you one can determine what we refer
10 to here as the NOEL and that refers to the no observed
11 effect level. In other words, it is the dose level in
12 the study which did not produce a toxic response.

13 And if you decide in advance what is an
14 appropriate safety factor between animals and man; that
15 is, let's say we were talking of birth defects by way
16 of example, and we decided that we would like a
17 thousand fold difference between the dose that you and
18 I might be exposed to as compared to the dose that the
19 animals were exposed to, we can determine in advance
20 that if we were looking at a teratology study we will
21 require a safety factor of one thousand. We can take
22 the lowest dose which did not produce an adverse effect
23 in that study, divide it by the appropriate safety
24 factor - which in this case we said might be a
25 thousand - and that would generate a number which we

1 call the acceptable daily intake.

2 In other words, the dose which did not
3 produce an effect divided by the safety factor is
4 clearly the dose which we would not consider to be
5 potentially toxic to humans.

6 If one is talking about exposure through
7 the food route one can go out and actually measure
8 residue. After typical agricultural application, one
9 can actually determine what the residue content of a
10 basket of food is and, in that way, one can determine
11 what the theoretical daily intake is of the chemical in
12 question.

13 Theoretical daily intake incidentally
14 tends to exaggerate what the actual daily intake is and
15 that has been the subject of some investigation by the
16 United States National Academy of Science.

17 I say it's somewhat exaggerated because a
18 theoretical daily intake makes a number of assumptions
19 which are --

20 THE REPORTER: Excuse me, Mr. Chairman. I
21 am going to have to ask Dr. Ritter to slow down again.

22 THE CHAIRMAN: Sorry, the reporter isn't
23 getting it all. Slow down again, please.

24 DR. RITTER: The theoretical daily intake
25 makes a number of assumptions, many of which we know

1 are probably not correct and it includes such
2 considerations as: All crop is treated all the time
3 all at maximum residue limits and all food products
4 that we consume have been treated with that chemical
5 all the time.

6 Now, it is very unlikely that all of
7 those conditions are always operating simultaneously.
8 In actual practice, frequently much of the crop has not
9 been treated, the residue is not present at the maximum
10 limit and we know that from actual surveys that have
11 been done in Canada and world-wide over many, many
12 years. Pesticide residues are rarely at the maximum
13 permitted level by law.

14 At any rate, that kind of an analysis
15 gives us what we call theoretical daily intake. Now,
16 if you recall how we define the acceptable daily
17 intake, clearly if the amount we are going to be
18 consuming is smaller than the amount we said is
19 acceptable, we have what we would consider to be a safe
20 use for food tolerance.

21 Again, if I could just repeat that this
22 calculation has built into it an additional safety
23 factor because the theoretical daily intake includes a
24 number of assumptions which we know will rarely, if
25 ever, all be operating at the same time. So that our

1 calculation of the theoretical daily intake represents
2 a value which is probably much greater or at least of
3 some measure greater than what the actual residue is in
4 food. So that if this theoretical daily intake is the
5 amount we expect to be exposed to through food is less
6 than the amount we said is all right, the use of that
7 product constitutes what we would call a safe use.

8 We can go through an analogous kind of
9 calculation or what I refer to as worker or bystander
10 exposure.

11 Again, if you would just imagine a line
12 between NOEL and safety factor, as we indicated
13 earlier, we can determine experimentally from the
14 studies that I have described what is the lowest dose
15 at which no adverse effects were seen. Once again, we
16 refer to that as the no observed effect level.

17 We can, again as we have discussed,
18 decide a priori what we would consider to be an
19 appropriate safety factor for any given effect that we
20 may be investigating. Once again, that regenerate will
21 be what we call an acceptable daily exposure; the
22 lowest dose which did not produce an effect divided by
23 a safety factor selected for that particular end point
24 gives us what we consider to be an acceptable exposure.

25 We can then go out and do exposure

1 studies. We can actually measure typical human
2 exposure during typical use of the chemical and we can
3 do that in an agricultural setting, we can do it in a
4 greenhouse, we can do it in a home, we can do it in a
5 forest, and we have done it actually in all of those
6 settings.

7 And from those exposure studies we can
8 determine what is the likely maximum exposure that
9 humans will be exposed to during that particular
10 application and like in the food example this would
11 give us what we call the theoretical daily exposure
12 using logic which is very analogous to the one that we
13 just described for food.

14 If the theoretical daily exposure, if the
15 exposure that we anticipate for applicators during the
16 normal course of their work is less than the level of
17 exposure which we have already judged to be safe, then
18 the use of that chemical in our view would be
19 considered safe.

20 This model --

21 THE CHAIRMAN: Excuse me. Does that take
22 into account any cumulative effect of being exposed to
23 the chemical?

24 DR. RITTER: The cumulative effects are
25 generally investigated in the pharmacology and

1 metabolism studies that I referred to earlier, so the
2 answer to your question is yes.

3 I should also add that the nature and use
4 of many of the chemicals which we described are used
5 relatively infrequently; they may be applied once or
6 twice a year; in the case of forestry they may be
7 applied once in 50 years. So that the opportunity for
8 cumulative effects with many of the uses of interest,
9 particularly to this Board, are not frequently
10 plausible.

11 We can go through a very analogous kind
12 of process for re-evaluation. The process that I
13 described for you refers to new chemicals that are
14 coming into the system today or within the recent past.
15 But of course, as you well know, there are many
16 chemicals that have been on the market for some years
17 and in order to try to capture what we know about these
18 chemicals and to ensure that all registered products in
19 Canada have a database which is analagous to the one
20 that I described for you, we have created a process by
21 which all registered products are re-evaluated on a
22 cyclical basis.

23 And the kinds of data that we require on
24 cyclical re-evaluation are very similar if in fact, in
25 many instances, not identical to the kinds of data that

1 I have already described for new products.

2 Very quickly just to review it for you
3 because I have covered only the toxicology data
4 requirements in the earlier review and, as you know,
5 there are many more data requirements than simply
6 toxicology. Data requirements might be include things
7 like product chemistry, what do we know about the
8 product per se, does the product have the potential to
9 be contaminated with such agents as sulphurdioxins;
10 analytical methods, can we actually analyse for the
11 presence of the chemical in the environment or human
12 tissue or in food; environmental fate - Peter Kingsbury
13 will have more to say about that - health effects,
14 which I have described for you to some length; the
15 animal toxicology, so on and so forth.

16 There is of course an involvement of the
17 various provincial agencies and other departments for
18 chemicals that have already been registered for some
19 time because we would very much like to benefit from
20 the actual use experience that may have been obtained
21 by use within various jurisdictions of this chemical
22 over the years.

23 And, finally, once all of this data has
24 been analysed we will, in some cases, identify data
25 gaps or data deficiencies and at that point in time the

1 petitioner, the registrant, the licensee will be
2 requested to submit this additional information and
3 where necessary to repeat studies which may be old and,
4 in our view, no longer sufficiently contemporary to
5 answer the kind of questions we would normally ask.

6 In addition to this process for
7 re-evaluation, in the last four or five years we have
8 carried out many what I will refer to as ad hoc
9 re-evaluations. They are ad hoc because they do not
10 comply with the regulations, the formal regulations and
11 law as far as re-evaluation is concerned and they are
12 ad hoc because they are driven primarily by one
13 concern. And I suppose the most notable example that
14 comes to mind for me of an ad hoc re-evaluation was the
15 case of alachlor and some of you may or may not be
16 familiar with the case of alachlor.

17 Alachlor was a corn and soyabean
18 herbicide which had been registered in Canada since
19 about 1969 and in the early 80s, around 1981 or 1982,
20 we became quite interested in a series of replacement
21 studies, such as the ones that I am referring to over
22 here, we became quite interested in the series of
23 replacement studies which had been submitted in support
24 of the continuing registration of alachlor.

25 On review of those additional studies, in

1 our view, the product constituted an unacceptable risk
2 which ultimately lead to the cancellation of this
3 product in Canada in 1985 which, in turn, was followed
4 by a very long and protracted legal battle ultimately
5 culminating by decision of Supreme Court of Canada in
6 its refusal to grant leave to appeal to Monsanto on
7 that matter.

8 That just ended within the last month or
9 two, so it was a process that took almost four years to
10 resolve completely. At this time that chemical is not
11 on the market in Canada. I mention that only because
12 it was not a formal re-evaluation, it was in fact an ad
13 hoc re-evaluation.

14 And we have perhaps carried out maybe 25
15 of those over the last four or five years, so that our
16 program of looking at the older registered chemicals
17 that have been used in Canada for some time may go
18 through either this formal re-evaluation process that I
19 have described for you - and there is a number of
20 examples of this - or it may go through the process of
21 ad hoc re-evaluations and there is a rather substantial
22 number of examples of that.

23 MRS. KOVEN: Excuse me, did you just say
24 that the informal -- the ad hoc process of
25 re-evaluations are 25 compounds or 25 substances that

1 have gone through that process?

2 DR. RITTER: I perhaps shouldn't quote
3 numbers, but I would say that they are probably
4 something of that order that have taken place in the
5 last four to six years.

6 MRS. KOVEN: In the formal re-evaluation?

7 DR. RITTER: In a formal re-evaluation,
8 the chlorophenoxy herbicides are presently in formal
9 re-evaluation and that constitutes several products
10 there were probably five, six, seven, eight, somewhere
11 of that order. In addition, the fumigants are in
12 formal re-evaluation and, again, that represents a
13 family of about five products.

14 And formal re-evaluations tend to be done
15 in clusters because what we want to avoid doing is to
16 eliminate the use of one chemical only to increase the
17 use of another about which we know a great deal less.
18 So that they tend to be done in clusters on chemicals
19 that have similar use patterns and, in addition, there
20 has been a formal re-evaluation for atrazine which has
21 been announced in the very recent past.

22 MRS. KOVEN: What did you mean by the
23 cyclical data for the formal re-evaluation?

24 DR. RITTER: There is a program in effect
25 which requires this re-evaluation to take place on a

1 cycle. There are, as I mentioned to you, about 450
2 active ingredients representing about 5,000 products or
3 so, and in order to come up with a logic which would
4 dictate the order in which these things were done, we
5 created a priority ranking scheme which included
6 considerations such as age of the data, the extent of
7 use, the likely exposure during use, and from the
8 interests of a variety of different departments, not
9 only our interest, but Environment Canada, Fisheries
10 and Oceans, so on and so forth, and that
11 priority-setting process created a cycle by which these
12 chemicals would be re-evaluated. The cycle does not
13 necessarily refer to time, but rather the process.

14 MRS. KOVEN: Can you give me some idea of
15 this process of re-evaluation and its size in
16 comparison to the registration of new products?

17 DR. RITTER: The registration of new
18 products is -- comparison of size to the formal
19 re-evaluation program or to the overall effort on
20 re-evaluation?

21 MRS. KOVEN: Both the ad hoc and the
22 formal re-evaluation, comparing that workload to the
23 size of what goes on with registration of new
24 substances.

25 DR. RITTER: I would say that in

1 comparison to the overall re-evaluation effort, both
2 formal and ad hoc, the activity in terms of effort is
3 probably close to equally divided between new products
4 and re-evaluation.

5 In terms of formal re-evaluation, I would
6 say that new products certainly get more attention.

7 MS. MURPHY: Q. And just before you go
8 on, you have explained the information that's required
9 on an original registration of the product?

10 DR. RITTER: A. That's correct.

11 Q. And you have explained information
12 that's required here at what you called a formal
13 re-evaluation of a registered product?

14 A. That's correct.

15 Q. And you've talked about the kinds of
16 things that happen in ad hoc re-evaluation?

17 A. Yes.

18 Q. And perhaps you could let us know,
19 and let me know if I am right, but is there any dataset
20 or any information required on a product that's already
21 registered if it's going to be used in a new way?

22 A. Yes, that was the last point that I
23 had intended to cover here.

24 There is a third category outside of the
25 registration of new products and the re-evaluation of

1 older ones which comes up on a day-to-day basis as well
2 and; that is, during the course of life of any given
3 product there is frequently applications for expansion
4 of use of that particular product.

5 In other words, a product may be
6 introduced initially to get rid of weeds in the
7 production of corn and shortly after that introduction
8 the company involved may request an expansion of that
9 original licence to include application to soyabeans,
10 and a year or two down the road may request yet another
11 expansion to include application to turf and so on and
12 so forth.

13 Our process of looking at these requests
14 for expansion of use involves a re-examination of the
15 available data every time we encounter an application
16 for expansion which, in our view, constitutes an
17 opportunity for increased exposure.

18 If I can just put that another way. If
19 the application for expansion merely involves the
20 inclusion of one more pest species on the label but
21 will not include any additional applications or any
22 additional crops, we will probably not be very
23 interested in it because that expansion; that is, if
24 the label already says - and the entomologist will have
25 to bear with me because I know very little about bugs -

1 if that initial application was to kill grasshoppers on
2 wheat and the expanded application is to kill
3 mosquitoes on wheat which occur at exactly the same
4 time, we would likely not wish to become involved
5 because that expansion in the label will not involve
6 any additional use of chemical for any additional
7 period of time.

8 On the other hand, if the initial licence
9 was to treat a particular weed in the production of
10 wheat and the subsequent application is to treat a weed
11 in the production of corn, we will most certainly
12 re-examine the available data because not only will
13 those -- will that proposed expansion involve
14 additional application of the chemical, it will involve
15 a whole new set of people because the farmers that are
16 producing wheat in western Canada are not the farmers
17 that are producing corn in central Canada.

18 On re-examination, if in our view the
19 available data is not sufficient to support a
20 contemporary registration, then historically we have
21 not been likely to agree with it, and at that time we
22 may frequently require submission of additional studies
23 to make the available data somewhat more contemporary
24 and reflect current standards.

25 MS. MURPHY: Q. Dr. Campbell was talking

1 about use patterns when he was giving his evidence.

2 Are the different things you are talking about, the
3 different kinds of uses of these products, is that
4 related in any way to that description of use patterns?

5 DR. RITTER: A. Yes, it is -- different
6 people use different terms to describe it, but
7 certainly use patterns is the correct way to describe
8 it. We tend to refer to it as use patterns.

9 If an application came in for an
10 insecticide - perhaps a more relevant example - to
11 treat spruce budworm in eastern Canada for a product
12 that may have already been registered in Canada for 15
13 years, we would not agree to such an application unless
14 in our view the available data reflected the kinds of
15 contemporary data requirements which we have in place
16 now.

17 Q. That's because you would be
18 considering that a new use pattern of the same product?

19 A. Well, for all -- we tend to consider
20 it really as a new product for all practical purposes,
21 even though it is already registered. Where the new
22 use in our view represents significant opportunity for
23 new exposure, we tend to see it as a new product for
24 all practical purposes.

25 And I should say as a matter of interest

1 that we have been criticized in some circles for having
2 done that because we have been accused of carrying out
3 re-evaluation in effect every time an expansion of use
4 request comes in. And I must say quite candidly, I
5 think to a large measure that's true of what we have
6 been doing.

7 I would like to spend a few moments
8 describing the exposure study which I briefly touched
9 on because I mentioned this is where we have made our
10 mark.

11 MS. MURPHY: Just before you do. For the
12 purposes of the record, this is Exhibit 710 that Dr.
13 Ritter is looking at now and I suspect he will be going
14 through that exhibit looking at each photograph and
15 giving it by number, 1 to 5, and perhaps with each one
16 you can just start by giving us a name or an
17 identifying description of the photograph.

18 DR. RITTER: All right. Let's call this
19 the base. When we do these exposure studies, as I have
20 indicated, we now require these studies of every
21 petitioner, every registrant who makes an application
22 for a new pesticide product in Canada. But, in
23 addition to that, we have carried out a number of these
24 studies on our own, both to help us understand the
25 complexities of them and to help us understand the

1 kinds of questions we should be asking of those that we
2 regulate when we ask them to do these studies. And in
3 this base slide what I am showing you is the kind of
4 clothing that we would generally provide to cooperators
5 in our study.

6 Now, in these kinds of studies what we
7 will do is to approach a number of people who may be
8 using this chemical anywhere; that is, I tend not to
9 think of these studies as human experimentation because
10 we are, generally speaking, approaching people who are
11 already making use of this chemical and, in most
12 instances, we are doing little more than asking them to
13 go about their usual business, allow us to carry out an
14 examination, perhaps donate some blood and, more often
15 than not, donate a week's supply of urine.

16 MS. MURPHY: Q. So this one could be
17 called the clothing used in exposure studies?

18 DR. RITTER: A. Well, we are going to
19 have more clothing. Why don't we call this the base
20 clothing.

21 Q. This is one with all of his clothes
22 on?

23 A. That's right. And we are going to
24 get to some that have a little less clothing on.

25 This is just a cotton outfit and we

1 supply this routinely because what we want to ensure is
2 that people coming into the study are not bringing
3 their old clothing which may already be contaminated
4 with a variety of pesticides, because ultimately we are
5 going to extract this clothing.

6 So this set of cotton overalls or two
7 pieces are supplied to everybody who is participating
8 in our study.

9 MRS. KOVEN: Excuse me, may I ask when
10 the word cooperators came to mean study subjects?

11 DR. RITTER: What it means in the study
12 subject?

13 MRS. KOVEN: When did that term come into
14 use?

15 DR. RITTER: I don't know. This is
16 informed consent. Honest. In addition to the overalls
17 that you see, we will then take a number of patches and
18 I should perhaps interject and say that there are a
19 number of ways in which human exposure studies can be
20 done and, in the interest of expediency, I'm only going
21 to present one because I'm using this really as a
22 generic example rather than as a specific case.

23 So I'm going to describe one patch method
24 and I will quickly add that there are other methods
25 which I am not describing but with which we are as

1 familiar as we are with this.

2 In this patch method, in addition to that
3 clothing what we will then do is to affix a series of
4 patches as you can see over here (indicating) to
5 various body regions, in addition to a personal air
6 pump, and I'm going to show you a close-up of that air
7 pump in a moment.

8 What these patches allow us to do is to
9 get an estimate of the amount of chemical that may fall
10 on various body regions and then through a series of
11 mathematical manoeuvres, which I'm going to tell you a
12 little bit about in a moment, that can then provide us
13 with an estimate of the amount of chemical that may
14 impact on different body parts and, consequently, where
15 should we concentrate our effort in an attempt to
16 reduce exposure to the chemical.

17 We have, for example, through studies of
18 this kind discovered over the last 8 to 10 years that
19 about 80 per cent of pesticide exposure in mixers and
20 loaders occurs to the hands. So that if one can find
21 some way to reduce or even eliminate exposure to the
22 hands, one has effectively eliminated 80 per cent of
23 pesticide exposure during the mixing and loading phase
24 of pesticide application.

25 MS. MURPHY: Q. So that one -- could we

1 call that one patches and air pump used in some
2 exposure studies?

3 DR. RITTER: A. Yes.

4 I would like to show you that air pump a
5 little closer. This is a personal air monitoring
6 device and it is driven by a nickel cadmium battery
7 which, in our hands, runs about 8 hours or so.

8 What we do is we attach a little piece of
9 tygon tubing to this thing and at the end of this is a
10 glass tube with a charcoal trap and this is then placed
11 around the breathing zone, particularly around the neck
12 of the cooperator.

13 What this device will do is it will suck
14 air through this opening over here (indicating) for the
15 period of application, so that at the end of the day we
16 can take not only the patches as well as the clothing
17 back to the laboratory and extract those, we can take
18 this carbon filter back to the laboratory, extract that
19 and, from that, we can then estimate the amount of
20 exposure that has taken place not only dermally but
21 through the inhalation route as well.

22 We know of course from first principles
23 that oral exposure is not likely to be a significant
24 route in workers, so we tend to be less concerned with
25 that route. We are, nevertheless, concerned with the

1 potential for inhalation exposure, consequently,
2 monitor the air around the breathing zone for a typical
3 day's work and we also are concerned with the amount of
4 chemical that may fall on different body parts.

5 Q. So that is a personal air monitoring
6 device?

7 A. Yes.

8 And the next one we are going to call
9 slides. I don't know if there is any people interested
10 in photography here today, but those patches which I've
11 shown you - I think we will call this patches perhaps -
12 are a little more than 2 by 2 slide mounts into which
13 we have placed a piece of surgical gauze. The back of
14 this has a piece of plastic strip behind it so that the
15 chemical that will fall on the gauze will then be
16 prevented from going straight through by the plastic.

17 Similarly, we have created a similar kind
18 of an arrangement that can be worn around ankles or
19 wrists or other areas in which the use of this kind of
20 a device is handier or can even be more reliable than
21 this kind of device.

22 We will call this centile man. This
23 centile man is from the National Aviation
24 Administration in the United States. From NASA and the
25 mathematical calculation that I referred to a moment

1 ago is based on centile man.

2 What this tells us is the proportion that
3 various body regions represent of the total. So that
4 we will know from this kind of a calculation, for
5 example, that the hands, while representing only 5.6
6 per cent of the available body surface for dermal
7 exposure, may represent 80 per cent of the overall
8 exposure to a given pesticide.

9 And this kind of centile man together
10 with the exposure study that I have described has been
11 very, very useful to us and to those that we regulate
12 in the last 8 or 10 years in determining; first, where
13 the bulk of exposure may take place and; secondly, what
14 would be the most effective means to reduce that
15 exposure.

16 And as you will note perhaps from my CV
17 over the last three or four years, we have put quite a
18 bit of effort in to determining the role of protective
19 clothing, what protective clothing is most effective
20 for retarding penetration of what kinds of chemical,
21 the effect of the non-active ingredient in the
22 formulation on retarding that uptake, and so on and so
23 on.

24 Finally, once these exposure studies have
25 been done -- the exposure study that I have described

1 for you, as I indicated, while it's an example it's
2 very representative of the kind of exposure studies
3 that are typically done in Canada and elsewhere. As I
4 have indicated to you, we require that those exposure
5 studies be done now in support of every new product
6 application, as well as in support of every major
7 product expansion of the type that we just discussed a
8 moment ago.

9 We would not be likely to agree to a
10 product expansion which involves significant
11 opportunity for increased exposure in the absence of
12 such an exposure study directly related to that
13 expanded use request.

14 Once the exposure data has been submitted
15 and the toxicology studies have been reviewed, we are
16 in a position to estimate what the likely risk is in
17 association with the use of that chemical. And in a
18 sense this is just another version of what you have
19 already seen earlier and I would like to just quickly
20 review the context of this both for food exposure and
21 for worker exposure.

22 As I mentioned to you earlier, toxicology
23 studies allow us to determine what is the lowest dose
24 level at which no adverse effects were seen in the
25 given study. And as we discussed, we can in advance

1 determine what is, in our view, an appropriate safety
2 factor, or perhaps to put it in another way, an
3 uncertainty factor. If we were testing these chemicals
4 in man there would be no need to determine the safety
5 factor and frequently when therapeutic drugs are
6 tested, there is no provision for a safety factor
7 because the test species is also the target species.

8 Because these chemicals are being tested
9 in rodents, small animals we always allow consideration
10 for the possibility that man is significantly more
11 sensitive than the test species and that is the basis
12 for these safety factors. That will give us again what
13 we consider an acceptable daily intake.

14 We know that the studies on which this no
15 observed effect level are based typically have been
16 carried out through the oral route of exposure, but we
17 also know that in the case of worker exposure, exposure
18 is often through the dermal route; infrequently, but
19 sometimes through the inhalation route and,
20 consequently, our safety factor must take account of
21 those differences in potential routes of exposure as
22 well.

23 Ultimately we know that in the case of
24 food at least that if the theoretical daily intake, the
25 amount that you and I would typically be exposed to

1 through consumption of food every day is less than what
2 we have already considered to be acceptable, that
3 represents a safe use.

4 A complication in trying to carry out
5 exactly the same calculation for workers is as I
6 mentioned that, whereas most of these studies are
7 conducted using the oral route of exposure in animals,
8 typically worker exposure by far and away the majority
9 of the time is through the dermal route and
10 infrequently through the inhalation route.

11 Consequently, in carrying out these safety factor
12 determinations we have made allowances for what that
13 difference in absorption may represent because of the
14 two different routes of exposure.

15 Once again, if in our view the
16 theoretical daily exposure which we have determined
17 experimentally from these human exposure studies is
18 less than what we have already considered to be
19 acceptable, then in our view the use of that chemical
20 should be safe.

21 Thank you.

22 MS. MURPHY: I have no further questions
23 at this time of Dr. Ritter, unless the Board has any.
24 It might be a good time just to take a break.

25 THE CHAIRMAN: Okay. We will take 15

1 minutes at this time.

2 We are planning perhaps to sit until five
3 or 5:15, in around that period where it's convenient to
4 break.

5 Thank you.

6 ---Recess taken at 4:05 p.m.

7 ---Upon resuming at 4:35 p.m.

8 THE CHAIRMAN: Thank you.

9 MS. MURPHY: Mr. Chairman, I thought I
10 would just first of all point out for the assistance of
11 everyone that the basic information that was just
12 presented without, of course, the examples and so forth
13 can be found in the paper written by Dr. Ritter and Mr.
14 Ormrod. That document is in the statement of evidence
15 for Panel 12. That is Exhibit 403A -- 603A, I believe.

16 MR. CASTRILLI: 603.

17 MS. MURPHY: 603A.

18 MR. CASTRILLI: Yes.

19 MS. MURPHY: That is Exhibit 603A and the
20 paper commences on page 80 of that document. And I had
21 a couple of minor questions that I did have for Dr.
22 Ritter before going to Mr. Kingsbury.

23 I would suggest, with your indulgence, if
24 I could do that and then perhaps suggest that we just
25 break and come back to Mr. Kingsbury perhaps early

1 tomorrow morning.

2 THE CHAIRMAN: Very well.

3 MS. MURPHY: Fine.

4 Q. Dr. Ritter, I just have a couple of
5 things I wonder if you could help me with. First of
6 all, I understood early in the presentation that you
7 were explaining that the data requirements are
8 collected pre-market; that is, that this information
9 must be collected before products are registered for
10 use and then, subsequently, when you were discussing
11 the exposure information, you were explaining that some
12 of the people who are involved in that were already
13 involved in using these products.

14 Can you explain that for me, please?

15 DR. RITTER: A. Yes. The pre-market
16 statement that I made referred to the toxicology data.
17 All of the toxicology studies which I described in
18 Canada must be submitted, evaluated and found to be
19 acceptable before the product is registered for general
20 broad scale use.

21 Exposure studies are done in two ways;
22 they are done in a generic context -- the ones that we
23 carry out are done in a generic context and they will
24 often, if not always, make use of specific products.

25 Q. That are already registered?

1 A. That's right.

2 Q. And so when you are explaining when
3 they are done in a generic context, I'm not entirely
4 clear what you mean.

5 A. The studies that we conduct are
6 conducted for the purpose of learning something about
7 the nature of the study rather than learning something
8 about exposure to a particular chemical. We have no
9 interest in exposure to a particular chemical. From
10 our vantage point, in the case of new chemicals,
11 exposure studies are almost always done during the
12 first year of experimental use after all of the
13 toxicology data has been submitted and evaluated.

14 Put it another way, we would not likely
15 agree to an exposure trial on an experimental use basis
16 if, in our view, the toxicology data did not reflect in
17 all likelihood the lack of a hazard in association with
18 that experimental trial.

19 THE CHAIRMAN: Dr. Ritter, because you
20 raised it and my information is thirdhand or hearsay
21 and probably not that reliable, but I want to ask these
22 questions because of the context in which you raised
23 it, and that was the alachlor ad hoc review that you
24 carried out.

25 As I understood that, the majority of the

1 testing was done in the U.S. and the product received
2 registration in the U.S. and subsequently in Canada.

3 One question is: Were independent tests
4 conducted in Canada on that product, or did the
5 Canadian authorities essentially rely on the results
6 from the American tests because, as I further
7 understand it, subsequently the lab that conducted some
8 of the testing in the U.S. was found to have
9 misrepresented some of the results leading to the U.S.
10 authorities cancelling the registration which then left
11 Canada in the position of deciding what they were going
12 to do with the fact that the product was registered
13 here but not registered in the U.S.

14 And, as a result of that, the independent
15 inquiry before the Alachlor Review Board was set up and
16 went through to what you indicate is the conclusion,
17 the Supreme Court of Canada's refusal for leave to
18 appeal.

19 But I guess my question is: When
20 products are registered in Canada for the first time,
21 are independent tests conducted by the Canadian
22 authorities which are different and in addition to any
23 other tests which have been conducted by some other
24 jurisdiction?

25 DR. RITTER: I would like to clarify some

1 of the things you have said, if I may, about the
2 alachlor case.

3 THE CHAIRMAN: And what I'm saying may be
4 totally inaccurate, it's basically what I have read in
5 newspapers, et cetera.

6 DR. RITTER: It is inaccurate. I would
7 like to correct it. As a matter of record, alachlor is
8 not cancelled in the United States and never has been.
9 It is registered today in the U.S. and has not been
10 registered in Canada since 1985.

11 We didn't follow the the Americans, we
12 led them. We were the first country in the world to
13 cancel use of alachlor. There are a number of
14 jurisdictions that have since followed suit but, to the
15 best of my knowledge, Canada was the forerunner to
16 remove alachlor from the market and today, 1989, it is
17 still registered in the United States.

18 The studies to which you refer initially
19 were conducted on behalf of Monsanto, the data owners
20 in the case of alachlor, by an organization called
21 Industrial Bio Test which came to be known as IBT and
22 in the mid-70s IBT, situated outside of Chicago, had
23 conducted many, many, many toxicologic studies on
24 behalf of many drug companies and pesticide companies.

25 In the latter 1970s it became evident

1 that there were a large proportion of studies conducted
2 by IBT which had been improperly conducted. In some
3 cases, it appeared that the data may have been randomly
4 generated in these studies. Alachlor was one of those
5 chemicals and, on examination, we requested rather
6 independently from the Americans, although through a
7 joint effort, that the various studies in question be
8 repeated.

9 It was the re-evaluation of those new
10 studies that were submitted starting about 1981 or so
11 that eventually led us to the conclusion that, in our
12 view, alachlor could not be used safely and
13 subsequently gave rise to the cancellation in February
14 of 1985. That was the situation with alachlor.

15 Specifically your question as to the
16 independence of testing, I want to make sure that you
17 and I use that phrase in the same context. All of the
18 studies which I have described are not conducted by
19 ourselves or the Americans or any other jurisdiction,
20 for that matter the testing requirement is imposed on
21 the petitioner and all of the studies are done either
22 by or on behalf of the petitioner and submitted
23 independently to regulatory agencies around the world
24 for evaluation and review.

25 So if I can take your question to mean:

1 answer is yes. We have never, to the best of my
2 knowledge, ever based a decision on an American review.

3 THE CHAIRMAN: And when you evaluate
4 studies which have been carried out by other labs in
5 other countries or in Canada, et cetera, and you are
6 evaluating results, can you come to the conclusion that
7 those results are valid having not done any independent
8 testing of your own.

9 In other words, you are accepting certain
10 numbers that come forward as a result of other labs
11 conducting the testing where you were not present when
12 that testing was carried out. So are you not accepting
13 at face value some of the raw data?

14 DR. RITTER: We are accepting all of the
15 data at face value. There are a number of checks and
16 balances that are in place to try to minimize or
17 eliminate the possibility that the Industrial Bio Test
18 situation could again repeat itself.

19 For example, in the early 1980s the
20 Governments of Canada and the United States implemented
21 something that will be referred to as GLP or Government
22 Laboratory Practice which is a tracking system from the
23 planning stage of the study through its execution and
24 final submission to regulatory agencies and the
25 auditing and bookkeeping which GLP requires and with

1 which studies must comply for submission, is designed
2 to minimize the opportunity for that kind of thing to
3 take place. In addition, there are world-wide audits
4 of laboratories which carry out studies on behalf of
5 both drug and pesticide petitioners.

6 I should add that the studies that we
7 receive are not necessarily American, they are
8 frequently European. Many of the companies that we
9 deal with are drug-based companies Cibe-Geigy, Dow
10 Chemical and so on and some for which are headquartered
11 frequently in Europe, so we tend to look at studies not
12 having a nationality.

13 The likelihood of fraud in these studies
14 is also reduced by the fact that studies are
15 simultaneously submitted to many regulatory agencies
16 worldwide. I tend to look at the IBT situation really
17 as one of our finest hours rather than as a weakness in
18 the system.

19 I think, as many regard it, it's true
20 enough that IBT carried out these, for lack of a better
21 term, fraudulent practices but I think if you recognize
22 perhaps that it was the regulatory agencies both in
23 Canada and United States that recognized that these
24 improper practices were going on really within a
25 relatively short period of time from when they started,

1 so I don't know if we can be held accountable for the
2 fraud, per se, but I think it's a credit to both our
3 system and to the Americans that the fraud became
4 evident very soon after it had been initiated.

5 THE CHAIRMAN: Okay, thank you.

6 MR. MARTEL: Could I ask a question.
7 What type of testing do you do on substances such as,
8 let's say -- or do you do any, for example, uranium or
9 asbestos where in fact there has been some serious
10 problems in Canada.

11 And I ask that in relationship to other
12 products that are on the market and whether they are
13 being pre-market tested, because my information, like
14 the Chairman's, is that some of this stuff doesn't get
15 pre-market tested.

16 DR. RITTER: The short answer is I don't
17 know. My interest in specialities over the last 10 or
18 12 years are really related to the regulation of
19 pesticides.

20 There is no question that in Canada the
21 registration of pesticides involves the pre-market
22 evaluation of toxicologic studies. That is most
23 certainly the case.

24 MR. MARTEL: You are not aware of other
25 chemicals that are coming on to the market annually?

1 DR. RITTER: No, I'm not.

2 MR. MARTEL: Can I ask one other
3 question. How do you determine the safety factor? In
4 your formula you have the safety factor. How is that
5 arrived at?

6 DR. RITTER: Largely through experience
7 in judgment and element of convention. If the minimal
8 safety factor that one tends to think of is the
9 smallest safety factor, one tends to impose what we
10 call a ten by ten matrix and that allows for a factor
11 of tenfold for interspecies and a factor of tenfold for
12 intraspecies.

13 That is a calculation that assumes that
14 there can be as much as a tenfold difference between
15 two rats and it further assumes that there can be
16 another tenfold difference between rats and men.

17 So if we were looking at a toxicologic
18 effect which we considered to be relatively trivial,
19 the minimum safety factor that we would impose would be
20 a hundred and then it would go up from there.

21 If we go to the extreme case, for
22 example, those agencies that apply safety factors to
23 carcinogens have often applied safety factors of the
24 order of 5,000 fold.

25 So to give you some point of reference,

1 one often sees safety factors that range from somewhere
2 around a hundredfold; whereas, as I say, those safety
3 factors of a hundredfold would be applied to effects
4 which we really don't consider to be worthy of a safety
5 factor at all. That's about the minimum safety factor
6 that we would apply, right up to about 5,000 fold for
7 the most serious consequences that we encounter.

8 MS. MURPHY: Q. I had one last question,
9 if you can help me with this one, because -- perhaps it
10 is a matter of semantics.

11 But you were talking about the NOEL, no
12 observable effect level, and you were explaining that
13 that level was the lowest dose that did not show a
14 toxic effect, and in considering it, isn't it possible
15 also to describe that as being the highest dose that
16 doesn't show a toxic effect? Can you explain --

17 DR. RITTER: A. Yes, it is, it is both
18 and it is a matter of semantics. It is sort of like
19 when we look at the results of a cancer trial we
20 consider the absence of an adverse effect to be a
21 negative result; that is, if no effect is demonstrated
22 in the study we consider that study to be negative.
23 Whereas the term negative, I think to most people,
24 implies that there was an adverse effect that was noted
25 to us. A positive study has an adverse effect.

1 What I meant by that phrase is the no
2 observed effect level, if one looks at a study for
3 example that has three dose levels and one control
4 untreated group, the dose level which I am referring to
5 as the no observed effect level might be that first
6 dose if the subsequent two have an effect.

7 I don't know if it would be easier if I
8 did that graphically. In a three-dose study, if the
9 top two doses have an effect and the bottom one does
10 not, the NOEL would be that bottom dose. Now,
11 depending on your point of view, that is either the
12 lowest dose or the highest dose.

13 Just very quickly without belabouring it,
14 if we have a study in which we have a control group and
15 a --

16 Q. Just hold on.

17 A. If we have a study in which we have a
18 control group, and this could be any study at all, it
19 doesn't really make a difference what the end point is.

20 MS. CRONK: I'm sorry, Mr. Chairman, both
21 to you and the panel and the witness. I wonder if I
22 could ask you, Dr. Ritter, if the Board doesn't object
23 to move that podium over so that some of us can follow
24 with you.

25 DR. RITTER: I'll tell you what I'll do,

1 if we have a blank transparency I can do it on there.
2 Would that be easier? I don't expect this is going to
3 take that long. If we have a study --

4 THE CHAIRMAN: Hold it. We need the
5 microphone again.

6 MS. MURPHY: I didn't really mean to
7 start this.

8 DR. RITTER: This is difficult to explain
9 in words, it is easier to explain graphically.

10 If we have a study, typically it might
11 involve three doses and an untreated control group and
12 the untreated control group is included so that we can
13 get some sort of sense of what might be occurring
14 spontaneously in the absence of any treatment at all.

15 So in a typical study we would have the
16 control group which receives no treatment at all, zero
17 treatment, and then we might have another group that
18 receives 10 units of the given chemical and another
19 group that might receive 50 units, and a third group
20 that might receive 100 units of the chemical in
21 question. And the control group in this particular
22 study, if we were testing 50 animals per dose per sex,
23 the control group in this particular study might have a
24 spontaneous rate of occurrence of this event of about 2
25 per cent, let's say, or 1 in 50.

1 The 10 group, if it were unaffected by
2 the treatment at this level, one would expect would
3 have a similar incidence of the particular effect that
4 we are studying, so it too would have an incidence of 1
5 per cent or 1 in 50.

6 The next group might have 20 out of 50
7 occurring and the final group might have 40 out of 50
8 occurring.

9 The no observed effect level in this
10 study would be this group here (indicating), the group
11 which had a frequency of events comparable to the
12 frequency occurring in the control group; the group
13 that did not receive any treatment at all.

14 Depending on one's semantics, this is
15 either the lowest dose which didn't produce the effect
16 or the highest dose tested which failed to produce that
17 adverse effect, but that's the group that I'm referring
18 to.

19 THE CHAIRMAN: And when you do that and
20 you take a sample of animals or rodents or whatever you
21 are testing on, what effect does the numbers that are
22 affected have with respect to whether or not that's
23 going to be an effect that you are going to recognize?

24 In other words, if it occurs in one test
25 specimen, is that enough; or are you going to say that,

1 you know, this is an aberration for this one and we
2 have done it a few times and it only occurred once and
3 that's enough?

4 DR. RITTER: The answer is yes and no.
5 There have been instances where a frequency of one is
6 sufficient to convince us that it is truly an effect
7 which is relateable to the treatment. There is a
8 variety of computations and permutations that one goes
9 through to try to answer that question.

10 For example, one of the things that one
11 may look at is what we refer to as a historical control
12 group. The control which I illustrated there would be
13 the concurrent control group, it is the group -- the
14 untreated group which is run simutaneously with the
15 treated animals. And all things being equal, one would
16 expect that that untreated group would react in exactly
17 the same way as the treated animals except for the
18 treatment.

19 But there are, of course, circumstances
20 that may sometimes serve to either depress the normal
21 background rate of the event or to elevate it, and to
22 try to examine that possibility one can look at a
23 historical control group.

24 If, for example, the laboratory in
25 question who has done, let's say, the cancer study, if

1 we go to Hazleton Laboratories, by way of example, a
2 big contract laboratory, they may at any time be
3 running 50 cancer studies.

4 So over the course of the last 10 years
5 they may have data from 3- or 400 hundred cancer
6 studies and we might look at the frequency with which
7 that event has occurred over the last 3- or 400
8 untreated control studies, and that gives us a sense of
9 whether or not the concurrent control is falling within
10 the kind of range that we would expect.

11 Although we place some importance on
12 statistical interpretation, it is not the definitive
13 answer. It is impossible to achieve a statistically
14 significant result for relatively rare events in
15 relatively small group sizes such as 50. So one need
16 not necessarily achieve a statistically significant
17 result to consider it biologically relevant.

18 I can think of some tumor events that we
19 have seen over the years where, in examining the
20 records maintained by the National Cancer Institute,
21 these events are known to occur with a frequency of
22 less than 1 in 5,000; that is, in 5,000 untreated
23 controls that have been examined it may have only
24 occurred once and if we see that event occur in a group
25 size of 50, we would be inclined to think that it is

1 relateable to treatment, even though the 1 in 50 may
2 still be a statistical anomaly, we would tend to
3 rely...

4 We also place quite a bit of importance
5 on the principle of dose response relationships and;
6 that is, that if it is truly an effect referable to the
7 treatment, one might expect that as one increases the
8 dose the frequency of the event would also increase.

9 So that both of those considerations are
10 taken in in determining what effects we would assign to
11 treatment and which effects we would assign to random
12 checks.

13 MR. MARTEL: Is it not difficult then to
14 determine, where you don't have large groups of people
15 exposed, to determine if in fact a cause of the
16 carcinogen is from the chemical possibly and not what
17 is anticipated in the general public?

18 Isn't that one of the big arguments that
19 always comes up, that in fact in small groupings, the
20 small operations, small plants, that the difficulty
21 becomes that there aren't enough workers there to
22 trigger what is normally anticipated in the general
23 public?

24 DR. RITTER: I'm not sure --

25 MR. MARTEL: In other words, if you get a

1 large operation and you have a lot of people that get
2 cancer, it is easy to some degree to say: Well, it's
3 attributable to some process or some substance, but
4 when you are dealing with small groups of people that
5 in fact it becomes very difficult to say with any type
6 of certainty: Aha, it is as a result of that because
7 that's what's anticipated or roughly anticipated in the
8 general public?

9 DR. RITTER: Well, actually it is the
10 converse that is more true. If one is dealing with a
11 relatively large population, the situation as much as
12 you have described, but if one is dealing with a
13 relatively small industrially exposed population such
14 as was the case, for example, some years ago with vinyl
15 chloride in which there was substantial industrial
16 exposure which took place some years ago, if one sees
17 the expression of a relatively rare event in a very
18 small population, that doesn't diminish your confidence
19 that it is relateable to treatment, quite the contrary;
20 it strengthens your belief that it is referable to
21 treatment, because if you are seeing the expression of
22 a rare event in a small population, the likelihood that
23 that is due to random chance is pretty remote.

24 If we are dealing with a tumor which has
25 a background rate -- let's talk about angiosarcoma for

1 a moment, which is a rare tumor of the liver which
2 occurs after exposure to vinyl chloride both in rodents
3 and in man. Now, if we were to say that the background
4 incidence, the spontaneous rate of occurrence of that
5 tumor - and I don't recall exactly what it is, but I
6 will pick a number which is probably reasonably
7 representative - if it were 1 in 3- or 400,000, what
8 that really means is that in a population of only 5,000
9 workers it is extremely unlikely that that tumor would
10 ever be seen.

11 Now, if in that industrial plant in the
12 case of 5,000 workers you suddenly see 10, that doesn't
13 diminish the belief that it was relateable to the
14 chemical, it is the other way around; it strengthens
15 the belief that it was relateable to the chemical.

16 MR. MARTEL: But in an industrial plant,
17 you would agree, that if you had 10 people with cancer
18 that you have got an outbreak?

19 DR. RITTER: That's right.

20 MR. MARTEL: I am talking about small
21 operations where there is 25 employees or 30 employees
22 and you only have one and the difficulty of trying to
23 establish a link between something -- knowing that
24 there is, what, 350 maybe known carcinogens in the
25 workplace, the difficulty of establishing a link to

1 that one individual's cancer and some chemical or
2 product in the workplace becomes very difficult because
3 at the same time there is an anticipated level in the
4 general public of that type of cancer anyway.

5 DR. RITTER: That's only partly correct.
6 If the general level anticipated is 1 in 100,000, for
7 example, and one sees an incidence of 1 in 25, it would
8 certainly make us curious as to whether or not that
9 reflected the normal background rate that we would
10 expect or some aberrant rate.

11 But I will tell you the real difficulty
12 in the situation that you described is not sorting out
13 the spontaneous rate from the induced rate, but rather
14 sorting out the exposure.

15 In most operations it's very, very, very
16 difficult to assign any effect to any given chemical
17 because in most human situations we are exposed to a
18 multitude of chemicals over a long period of time, and
19 at the end of the day to assign any particular effect
20 to any particular chemical is very difficult unless the
21 effect is sufficiently uncommon that it is unlikely
22 that it could be referred to anything except a specific
23 exposure.

24 And the example I gave you was one,
25 angiosarcoma, hepatic angiosarcoma and vinyl chloride

1 is virtually a fingerprint. Where one sees hepatic
2 angiosarcoma it is almost most certainly referable to
3 exposure to vinyl chloride. The other would be
4 pulmonary mesothelioma which is seen on exposure to
5 asbestos.

6 MR. MARTEL: Oh, wait a minute. I don't
7 want to get into an argument, but that is one of the
8 most difficult ones to prove when you go to the
9 Compensation Board, that in fact it is related to the
10 exposure to asbestos.

11 DR. RITTER: I think you are referring to
12 the difficulty in proving that it is related to an
13 industrial exposure to asbestos.

14 MR. MARTEL: Right.

15 DR. RITTER: No, that's not what I said.
16 I said that where you see mesothelioma.

17 MR. MARTEL: Yes.

18 DR. RITTER: You can say with some degree
19 of certainty that exposure to asbestos has taken place.
20 I didn't say you could say it took place in the
21 workplace.

22 MR. MARTEL: Oh I understand that, but
23 having gone through the exercise many, many times...

24 DR. RITTER: It's like main stem bronchis
25 lung tumors and smoking. There are many, many kinds of

1 lung tumors that are diagnosed routinely, but there is
2 really only one kind of lung tumor that is most
3 frequently found in association with smoking.

4 So that when one diagnoses this tumor one
5 can say with a reasonable degree of certainty that
6 there has been a prolonged period of smoking in that
7 individual's history. You can't say it is absolutely,
8 but you can certainly say it biologically with a fair
9 degree of confidence. These are fingerprinting types
10 of tumors.

11 The same is true for many chemicals. We
12 know that certain groups of chemicals are capable of
13 inducing certain birth defects and other groups of
14 chemicals are responsible for inducing another set
15 of -- another kind of birth defects. So that when one
16 sees a specific kind of birth defect one can speculate
17 with some certainty that exposure to this type of
18 chemical in all likelihood has taken place. In fact,
19 one can even say something about when during pregnancy
20 the exposure probably took place.

21 MS. MURPHY: Well, I certainly don't have
22 any more questions. May I suggest we come back early
23 tomorrow morning, Mr. Chairman.

24 THE CHAIRMAN: Okay, we will adjourn
25 until 9:00 a.m.

1 Thank you.

2 MR. CASTRILLI: Mr. Chairman, could I
3 just get an indication from Ms. Murphy how long she
4 will be in-chief with Mr. Kingsbury?

5 MS. MURPHY: Well, I can tell you that
6 Mr. Kingsbury speaks a little slower than Dr. Ritter,
7 but we could be -- well, we won't be any longer than
8 the morning. I think I can assure you of that.

9 MS. CRONK: I should say, Mr. Chairman,
10 if this is of any assistance to Mr. Castrilli, that
11 depending upon when Ms. Murphy completes her
12 examination-in-chief of Mr. Kingsbury I may ask the
13 Board for some time to consider that direct examination
14 in the hopes that I hear part of it today, but
15 depending on when that is, obviously I don't want to
16 inconvenience the Board.

17 THE CHAIRMAN: Very well. But in all
18 likelihood we should be able to finish with your
19 cross-examination tomorrow, I would think.

20 MS. CRONK: I would hope so, sir, but of
21 course I can't guarantee it.

22 MR. CASTRILLI: So I can assume that I
23 will probably not start before late tomorrow?

24 THE CHAIRMAN: It looks unlikely. Thank
25 you.

1 ---Whereupon the hearing adjourned at 5:10 p.m., to be
2 reconvened on Wednesday, August 9th, 1989,
3 commencing at 9:00 a.m.
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